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Expert Report of Professor Jonathan Gruber

March 25, 2019

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I. Qualifications

1. My name is Jonathan Gruber, and I am the Ford Professor of Economics at the Massachusetts Institute of Technology, where I have taught for more than 25 years. I received my Ph.D. in Economics from Harvard University in 1992 and my B.S. in Economics from MIT in 1987.

2. I specialize in the economics of health and public finance. I have more than 170 published articles, including articles that in 1995 and 2013 won the International Health Economics Association Kenneth J. Arrow Award for the outstanding health economics paper of the previous year. I am the author of the leading textbook in the field of Public Finance, *Public Finance and Public Policy* (now in its fifth edition). I have served as the Co-Editor for both the Journal of Public Economics and the Journal of Health Economics, and as Associate Editor for those journals as well as the American Economic Journal: Economic Policy. I have for many years taught Public Finance and Microeconomics at MIT.

3. In addition to my academic responsibilities, I direct the Health Care Program at the National Bureau of Economic Research, the nation's leading academic economic think tank. I have received many honors and awards over the course of my career. I served as President of the American Society of Health Economists (ASHEcon) from 2016-2018. Along with David Cutler, I won the ASHEcon award for best health economist in the nation age 40 and under in 2006. I am a Fellow of the Econometric Society, a member of the American Academy of Arts and Sciences and the Institute of Medicine. In both 2006 and 2012 I was named one of the 100 most powerful people in health care by Modern Healthcare magazine and I was named "One of the Top 25 Most Innovative and Practical Thinkers of Our Time" by Slate Magazine in 2011.

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4. I have also been an active participant in the development of health care policy in the United States at the federal and state level for more than two decades. I worked on a variety of health care issues, including the development of the S-CHIP program, as a member of the Clinton Administration Treasury Department in 1997-1998. I was an advisor to both Governor Romney and the Massachusetts legislature in developing Massachusetts health care reform, and an inaugural member of the Connector Board that implemented that legislation. I was also a consultant to the Obama Administration during development of the Affordable Care Act and I am the author of *Health Care Reform: What It Is, Why It's Necessary, How it Works*.

5. My work in health economics also includes extensive work on addictive behaviors, including significant academic work, federal policy experience, and expert testimony experience in the economics of smoking. I have written more than a dozen academic papers on the economics of, and government policy towards, smoking. I have been retained as an expert witness and consultant in a variety of prior cases, including as an expert witness on behalf of the Department of Justice in *Department of Justice vs. Philip Morris*, for a series of state cases against non-participating manufacturers in the Master Settlement Agreement (MSA), and for the Non-Participating Manufacturers Adjustment proceedings of the MSA.

6. My curriculum vitae, which provides additional detail about my career, publications and prior expert testimony is attached as **Appendix I.A**. My billing rate in the matter is \$1,000 per hour. In preparing this report, I and staff under my direction: analyzed data; reviewed economic literature, court filings, documents produced in this litigation, and deposition testimony. My compensation is not dependent on the outcome of this proceeding. In addition

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to the information cited herein, a list of the documents reflecting the facts and data that I have considered on in formulating my opinions is attached as **Appendix I.B.**

II. Introduction, Assignment and Methodology, and Summary of Opinions

A. The Opioid Crisis

7. Opioid abuse has become the signal public health crisis of the 21st century in America.

The U.S. Department of Health and Human Services (HHS) estimates that 11.4 million Americans took opioids and that 2.1 million people in the U.S. suffered from Opioid Use Disorder (OUD) in 2017.¹ And increasingly the consequences of OUD are illustrated in opioid related deaths. In 2017 alone, more than 47,600 Americans died from opioid-related overdoses, a total greater than peak annual deaths due to H.I.V or guns.² The rate of opioid-related deaths continues to accelerate: the rate of U.S. opioid-related mortality (defined as deaths per 100,000 adults) grew from 3.4 in 1995 to 11.4 in 2010, to 20.5 in 2017.³ Between 2015 and 2017 alone, the opioid related mortality rate grew by more than 34 percent.⁴

8. The size of other drug crises in U.S. history pale in scope compared to the current opioid crisis. In contrast to the 47,600 opioid-related deaths in 2017, fewer than 3,000 individuals died of crack cocaine overdoses at the height of that epidemic in the late 1980s annually.⁵ While

¹ SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results From the 2017 National Survey on Drug Use and Health," available at <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>.

² H.I.V. related deaths peaked in 1995 at approximately 43,000 and gun deaths in 2017 at approximately 40,000. NCHS mortality data accessed on CDC Wonder.

³ Calculated from NCHS Multiple Cause of Death data based on opioid-related deaths as a percentage of the population ages 15 and older.

⁴ NCHS mortality data.

⁵ NCHS mortality data accessed on CDC Wonder; US General Accounting Office, "The Crack Cocaine Epidemic: Health Consequences and Treatment," January 1991, p. 14, available at <https://www.gao.gov/assets/90/89031.pdf>.

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methamphetamine deaths continue to rise in the U.S., there were only 5,130 deaths involving methamphetamines (and not opioids) in 2017, less than 11 percent of the opioid-related total.⁶ The escalating opioid crisis has contributed to declines in life expectancy in the U.S. for the first time since World War II.⁷

9. While overdose deaths are a striking manifestation of the opioid crisis, the consequences of the crisis are felt much more widely. A variety of studies examine the social costs in the U.S. that have resulted from the opioid epidemic.⁸ For example, a recent study undertaken by the Council of Economic Advisors (CEA) found that the opioid epidemic has resulted in an additional annual cost of \$72.3 billion in healthcare costs, criminal justice costs, and lost productivity due to opioid misuse.⁹ Florence, et al. (2016) estimate increased healthcare costs from opioid abuse of \$28.9 billion, increased criminal justice costs of \$7.6 billion, and lost productivity from OUD of \$20.4 billion for the year 2013 alone.¹⁰ The CEA also

⁶ NCHS mortality data accessed on CDC Wonder. Data exclude methamphetamine deaths that also involved opioids. Another 5,200 overdose deaths in 2017 involved both methamphetamines and opioids.

⁷ <https://www.cdc.gov/nchs/data/databriefs/db328-h.pdf>; Josh Katz and Margot Sanger-Katz, "'The Numbers Are So Staggering.' Overdose Deaths Set a Record Last Year," *The New York Times*, November 29, 2018, available at, <https://www.nytimes.com/interactive/2018/11/29/upshot/fentanyl-drug-overdose-deaths.html?smtyp=cur&smid=tw-nytimes>.

⁸ See, e.g., The Council of Economic Advisors. "The Underestimated Cost of the Opioid Crisis." (2017) (CEA (2017)); Florence, Curtis S., Chao Zhou, Feijun Luo, and Likang Xu. "The economic burden of prescription opioid overdose, abuse, and dependence in the United States, 2013." *Medical Care* 54 (2016): 901-906 (Florence, et al (2016)); Kirson, Noam Y., Lauren M. Scarpatti, Caroline J. Enloe, Aliya P. Dincer, Howard G. Birnbaum, and Tracy J. Mayne. "The economic burden of opioid abuse: updated findings." *Journal of Managed Care & Specialty Pharmacy* 23 (2017): 427-445 (Kirson, et al (2017)); and Birnbaum, Howard G., Alan G. White, Matt Schiller, Tracy Waldman, Jody M. Cleveland, and Carl L. Roland. "Societal costs of prescription opioid abuse, dependence, and misuse in the United States." *Pain Medicine* 12 (2011): 657-667 (Birnbaum, et al (2011)).

⁹ CEA (2017), Table 2.

¹⁰ Florence et al (2016), Table 3.

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estimated over \$430 billion in losses as a result of fatalities from opioid overdoses in 2015 alone based on estimates of the value of a statistical life from the economic literature.¹¹

B. Assignment and Methodology

10. I understand this litigation was brought by a variety of different governmental entities, including county and city governments. I further understand that trial will focus on the claims alleged by Cuyahoga and Summit Counties, both in Ohio (also referred to herein as “Bellwether jurisdictions”, “Bellwether governments”, “Bellwether communities”, or “Bellwether plaintiffs”). The Bellwether governments allege that the defendants’ “conduct in promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin.”¹² The Bellwethers governments further allege that the opioid epidemic and the need for increased services to address it, “arose from the opioid manufacturers’ deliberately deceptive marketing strategy to expand opioid use, together with the distributors’ equally deliberate efforts to evade restrictions on opioid distribution.”¹³ In addition, the Bellwether governments allege that manufacturer defendants “manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders” and distributor defendants “distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of

¹¹ CEA (2017), p. 6.

¹² In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-OP-45004, Second Amended Complaint, May 18, 2018, (“Cuyahoga Complaint”), ¶19; In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 18-OP-45090, Corrected Second Amended Complaint and Jury Demand, May 18, 2018, (“Summit Complaint”), ¶20.

¹³ Cuyahoga Complaint, ¶3, Summit Complaint ¶3.

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wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes.”¹⁴

11. Two economic questions arise in connection with these allegations: *First*, is it possible to evaluate from an economic perspective the extent to which the actions of the defendants contributed to this epidemic. *Second*, is it possible to estimate the damages to the Bellwether government entities resulting from the defendants’ actions using principles of applied economics.

12. As set forth below, this report addresses certain aspects of these two questions. In particular, this expert report presents, from an economic perspective, an overview of the opioid crisis and opinions about the impact of shipments of prescription opioids on opioid misuse. The analysis focuses on opioid-related mortality -- one of the most important, and socially costly, aspects of the crisis. My analysis establishes both how shipments of prescription opioids led to dramatic increases in misuse of and mortality due to prescription opioids, and how the prescription opioid crisis led to the dramatic increase in mortality from illicit opioids, principally heroin and fentanyl, after 2010. As described below, my analysis demonstrates that the illicit opioid crisis that has emerged since that time is directly related to the defendants’ earlier shipments of licit prescription opioids. This report also addresses the relationship between shipments of prescription opioids by the defendants and increases in violent and property crime rates.

¹⁴ Cuyahoga Complaint, ¶¶36, 81, Summit Complaint ¶¶63, 107.

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13. Other economists will also be submitting expert reports addressing certain aspects of the above-referenced questions. For example, the Expert Report of Professor Meredith Rosenthal of Harvard University (the “Rosenthal Report”), presents an econometric analysis of the relationship between the promotional efforts of the defendants and shipments of prescription opioids.¹⁵ The Expert Report of Professor David Cutler of Harvard University (the “Cutler Report”) establishes a framework for evaluating the impact of increased shipments of prescription opioids on social harms experienced in Bellwether jurisdictions, including those related to crime, public safety and health, and child protection. Professor Cutler’s analysis is based in part on the Rosenthal Report. The Expert Report of Professor Thomas McGuire of Harvard University (the “McGuire Report”) estimates damages to Bellwether jurisdictions. Professor McGuire’s analysis is based in part on the Cutler Report and the Rosenthal Report.

14. Taken together, the analyses presented in these reports yield estimates of damages resulting from defendants’ misconduct, including misleading marketing actions as well as the failure of all registrants of the Controlled Substance Act (“CSA”), including distributors of prescription opioids, to maintain effective controls against diversion.¹⁶ Analyses presented below establish that per capita shipments of prescription opioids varied widely across

¹⁵ I understand a separate report will present an estimate of the share of shipments that distributor defendants could reasonably have been expected to identify as excessive and/or potentially suspicious, but that this report does not need to be disclosed until April 15, 2019. The analysis of the impact of shipments on social harms in the Expert Report of Professor David Cutler and the damages analysis in the Expert Report of Professor Thomas McGuire will rely on the results reported by Professor Rosenthal and this separate report.

¹⁶ Because aspects of analyses presented in McGuire Report, Cutler Report and Rosenthal report are related to each other, the following numbering convention is adopted to identify tables, appendices and back up materials from each report: Materials related to this report are identified with the prefix I (e.g., Figure I.1); materials related to the Rosenthal Report use the prefix II; materials related to the Cutler Report use the prefix III; and materials related to the McGuire report use the prefix IV.

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geographic areas that are otherwise comparable in terms of population demographics. This pattern indicates that many such shipments of prescription opioids were potentially suspicious and that such shipments were not identified and prevented by CSA registrants. This in turn suggests that a potentially substantial share of harms associated with shipments of opioids due to manufacturers' misconduct could have been avoided if CSA registrants including distributors had met their obligations to monitor and prevent excessive shipments.

15. I have been asked by counsel for the Bellwether plaintiffs to specifically address the following topics in this report. First, I have been asked to provide, from the perspective of accepted principles of economics, an overview of the nation's opioid crisis. Second, I have been asked whether, to a reasonable degree of certainty in the field of economics, the defendants' shipments of prescription opioids contributed, in whole or part, to the growth in the misuse of opioids and the increases in licit and illicit opioid-related mortality over the past 20 years, and to explain the bases for my opinion.

16. My analysis draws on a wide variety of sources and establishes to a reasonable degree of certainty in the field of economics that:

- There is a direct, causal relationship between defendants' shipments of prescription opioids and the misuse and mortality from prescription opioids, with geographic areas that received higher volumes of per capita shipments of prescription opioids experiencing significantly higher rates of opioid related misuse and mortality, including the Bellwether jurisdictions.

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- There is a direct, causal relationship between defendants' shipments of prescription opioids and the misuse of and mortality from illicit opioids, including heroin and fentanyl, which accelerated rapidly after 2010. As has been widely recognized in the economic literature, the growth in the dependence on prescription opioids from the early 1990s to 2010, coupled with a variety of factors starting in and around 2010, created an increased demand for illicit opioids, including heroin and later fentanyl. These factors included the release of an abuse deterrent formulation (ADF) of OxyContin, the increase in state-level prescription drug monitoring programs, caps on opioid prescribing, and law enforcement investigation and prosecutions against pill mills throughout the country. Illicit opioids are chemically similar to prescription opioids and thus a substitute sought by individuals addicted to prescription opioids following the restrictions in the supply of prescription opioids.
 - Available data indicate that illicit opioid mortality grew more in areas that received more shipments of prescription opioids.
 - Epidemiological studies further establish that, in contrast to prior decades, a large majority of individuals that misuse heroin today took prescription opioids before moving on to illicit opioids.
 - In sum, increases in the demand for illicit opioids, and the associated increases in mortality, would not have occurred in the absence of the enormous increase in prescription opioid shipments resulting from

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defendants' misconduct, which effectively created a stock of individuals susceptible to illicit opioid use and abuse.¹⁷

- The significant increases in all-opioid mortality (i.e., mortality from both prescription and illicit opioids) are largely unrelated to trends in non-opioid drug overdoses, changes in population demographics, or local economic conditions. Available data indicate that deaths from all opioids grew far more rapidly than non-opioid overdose mortality since the mid-1990s and that opioid mortality trends are similar in areas with different trends in economic activity. This conclusion is also consistent with existing economic literature.

17. I address these questions from the perspective of applied microeconomics and, more specifically, health economics. Health economics is an established subfield in economics with its own national and international organizations, specialized journals, textbooks, and undergraduate and graduate level courses. The field of health economics focusses on a wide variety of topics, often with an empirical focus. Examples include analysis of markets for pharmaceuticals, physician behavior and consumer behavior involving products that involve health risks such as cigarettes, alcohol and illicit drugs. The field of health economics also includes a vast literature analyzing mortality and morbidity.

¹⁷ I understand that defendants' knowledge of addiction risks associated with prescription opioids is discussed in the accompanying expert reports of Dr. Theodore Parran and Dr. Anna Lembke.

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18. My analysis is ongoing, and I reserve the right to supplement or modify it based on new materials or testimony that may become available to me, including, but not limited to, other expert witness reports that have not been produced prior to the completion of my assignment.

19. The remainder of this report is organized as follows:

- Section III provides an empirical overview of the opioid crisis, including an evaluation of how the crisis evolved from one involving prescription opioids to one involving both prescription and illicit opioids.
- Section IV presents evidence from a variety of sources that establishes that increases in opioid-related mortality are the direct consequence of shipments of prescription opioids.
- Section V presents additional evidence that the illicit opioid crisis was the consequence of shipments of prescription opioids.
- Section VI establishes that shipments of prescription opioids are also associated with higher crime.

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III. Factual Background and Empirical Overview of the Opioid Crisis

A. The Growth of Prescription Opioid Shipments and Opioid Misuse from an Economic Perspective

1. Opioid Use and Trends: Pre-1995

20. Opioids have long been used to treat pain in the U.S. and around the world – as well as having long been abused, leading to addiction and death.¹⁸ Morphine became a widely used pain treatment during the 19th century, but its harmful aspects were already recognized and led to the search for an ostensibly non-addictive form.¹⁹ Heroin was initially introduced in the late 19th century as a non-addictive alternative to morphine, but it soon became clear that heroin was addictive as well.²⁰ This resulted in early 20th century regulation in the U.S. that greatly limited the use of morphine and heroin as pain treatments.²¹

21. I understand that the Expert Report of David Courtwright documents two subsequent heroin crises in the U.S in the 20th century – one during the late 1940s and early 1950s, and a larger crisis in the late 1960s and early 1970s.²² As discussed below, the illicit nature of drug use makes it difficult to estimate the number of persons that abuse heroin and prescription opioids, either today or in the past. However, analysts from RAND estimate that as of 2010

¹⁸ Erick Trickey, “Inside the Story of America’s 19th-Century Opiate Addiction,” *Smithsonian Magazine*, January 4, 2018, available at <https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/>; Expert Report of David Courtwright, February 8, 2019 (“Courtwright Report”), pp. 90-91.

¹⁹ History.com Editors, “Heroin, Morphine and Opiates,” last updated August 21, 2018, available at <https://www.history.com/topics/crime/history-of-heroin-morphine-and-opiates>.

²⁰ United Nations Office on Drugs and Crime, “History of Heroin,” available at https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1953-01-01_2_page004.html; History.com Editors, “Heroin, Morphine and Opiates,” last updated August 21, 2018, available at <https://www.history.com/topics/crime/history-of-heroin-morphine-and-opiates>.

²¹ United Nations Office on Drugs and Crime, “History of Heroin,” available at https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1953-01-01_2_page004.html.

²² I also understand other experts discuss the history of heroin abuse in this country, including Dr. Anna Lembke and Dr. Ted Parran.

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roughly 1.5 million people regularly used heroin, and that figure does not account for the large increases in illicit opioid use since 2010. In contrast, available studies indicate that there were roughly 110,000 opioid addicts in the United States in 1967, during the earlier heroin epidemic mentioned above.²³

22. The addictive potential for opioids is long established in the medical literature.²⁴ The active molecule in prescription opioids has similar physiological effects to those in heroin.²⁵ As a result, throughout most of the twentieth century, physicians have prescribed opioids only in limited circumstances involving acute pain such as palliative, cancer and post-surgical care.²⁶

23. As of the early 1980s, the medical profession maintained a highly conservative approach to the use of opioid in pain management. As I understand Dr. Courtwright's report explains, the medical community and regulators were heavily focused on risks associated with opioids and imposed restrictions on the use of opioids, including methadone, which was seen as raising risks of diversions and overdoses. However, around that time, manufacturers of prescription opioids and some physicians, including those affiliated with the manufacturers, started to advocate for more aggressive use of opioids in managing pain for a broader range of patients, including treatment of chronic pain.

²³ Estimate from Ball, John C., David M. Englander, and Carl D. Chambers. "Chapter 4: The Incidence and Prevalence of Opiate Addiction in the United States." In *The Epidemiology of Opiate Addiction in the United States*, edited by John C. Ball and Carl D. Chambers, 68-78. Springfield, IL: Charles C. Thomas, 1970, p. 78.

²⁴ I understand that this is addressed in the accompanying expert report of Dr. Katherine Keyes.

²⁵ See, for example, Kosten, Thomas R., and Tony P. George. "The neurobiology of opioid dependence: implications for treatment." *Science & Practice Perspectives* 13 (2002).

²⁶ I understand that this is addressed in the accompanying expert report of Dr. David Courtwright.

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24. Initially, this movement did not result in major changes in the medical use of opioids during the 1980s, with per capita shipments growing by just over 4 percent annually between 1980-90.²⁷ Efforts by physicians to manage pain more aggressively through the 1980s and early 1990s were actively supported by participants in the pharmaceutical industry, including some defendants to this litigation. The industry's support was three-pronged and involved: (1) identifying and supporting medical advocates most favorable to active pain management and opioids; (2) influencing professional medical organizations and regulatory bodies that established and enforced standards of care in pain management; and (3) using public relations techniques to gain public support for pain awareness, patient advocacy and opioid treatment.²⁸

2. The Growth in Shipments Since 1995

25. Efforts to promote use of opioids in pain management accelerated with the launch of OxyContin in 1995. I understand that the Expert Report of Matthew Perri documents how the pharmaceutical companies engaged in an extensive marketing campaign to overcome physician reticence to prescribe opioids. Defendants also targeted physicians by marketing to them indirectly, through associations with advocacy organizations such as the American Pain Foundation, American Pain Society and the American Association of Pain, which allowed them to deliver unbranded marketing messages about the safety and efficacy of opioids to physicians.²⁹

²⁷ National shipment data provided from International Narcotics Control Board (INCB), available at https://web.archive.org/web/20151009170340/http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/country_files/morphine_equivalence/unitedstatesofamerica_me.pdf.

²⁸ I understand that this is addressed in Dr. Courtwright's Expert Report.

²⁹ I understand that this is addressed in Dr. Courtwright's Expert Report.

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26. I further understand that the Expert Report of Matthew Perri indicates that the well-meaning intentions of some physicians combined with active support of their efforts by pharmaceutical companies and aggressive marketing of opioids resulted in changes in medical policies to encourage more active pain management. In 2001, the Joint Commission – which sets standards for and accredits health care organizations and programs – encouraged more active pain management by introducing standards for doctors and medical organizations to improve care related to pain.³⁰ The Joint Commission standards also provided examples of implementation, including one that recognized pain as a “fifth vital sign” to be evaluated by physicians along with heart rate, temperature, respiratory rate and blood pressure.³¹ This followed the Veterans Administration implementation of a mandate to assess pain as the fifth vital sign in 2000, including the use of 0-10 point Numerical Rating Scale.³²

27. This period of promotional increase was associated with dramatic growth in the shipments of prescription opioids. **Figure I.1** shows the aggregate rise in per capita shipments in prescription opioids in the U.S. from 1997, the first year for which data on shipments of prescription opioids from the Drug Enforcement Administration’s Automation of Reports and Consolidated Orders Systems (ARCOS) data are available, through 2016.³³ These data indicate

³⁰ David W. Baker, “The Joint Commission’s Pain Standards: Origins and Evolution,” Division of Healthcare Quality Evaluation, The Joint Commission, May 5, 2017, available at https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

³¹ David W. Baker, “The Joint Commission’s Pain Standards: Origins and Evolution,” Division of Healthcare Quality Evaluation, The Joint Commission, May 5, 2017, available at https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

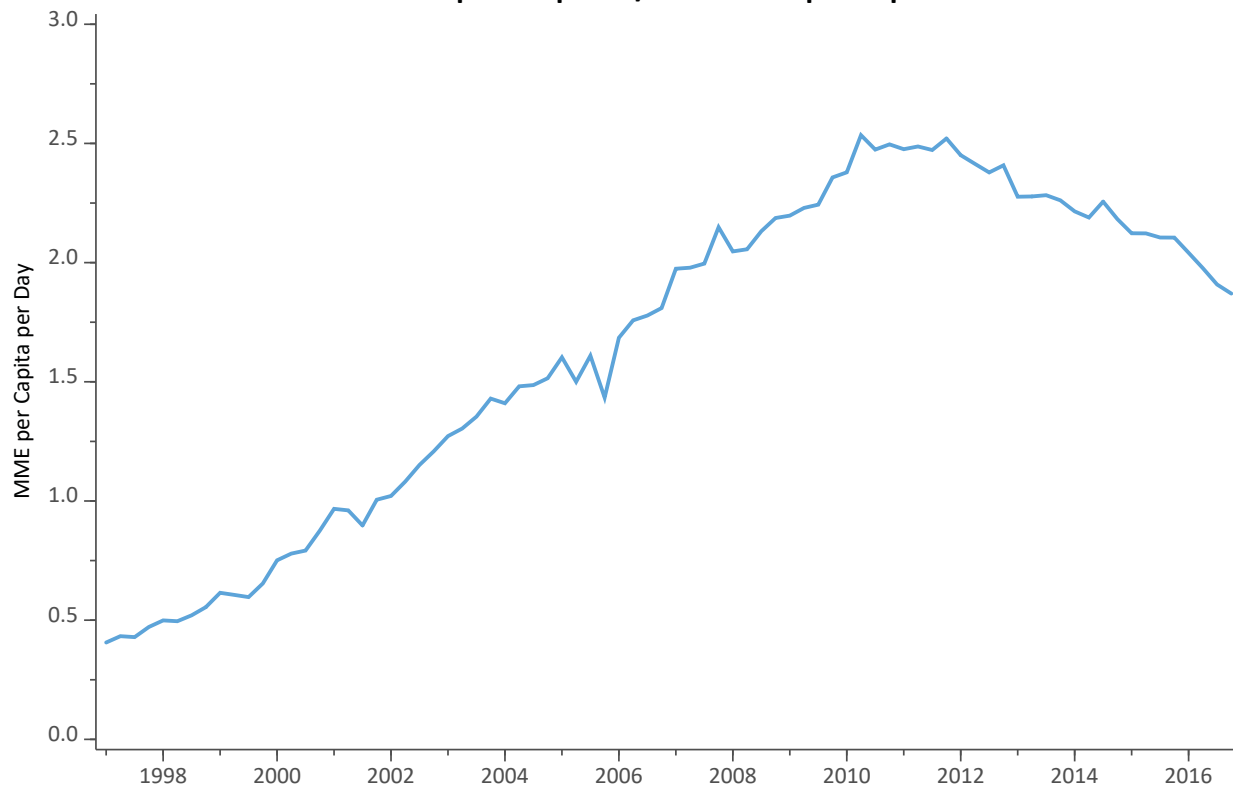
³² Department of Veterans Affairs, “Pain as the 5th Vital Sign Toolkit,” October 2000.

³³ **Appendix I.C** provides notes about the analysis presented in this figure and other figures in this report.

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that shipments of prescription opioids (measured in MMEs per capita per day) increased by more than 500 percent between Q1 1997 and Q4 2010.³⁴

Figure I.1
Shipments of Prescription Opioids in the U.S.: 1997-2016
All Prescription Opioids/MME Units per Capita



Source: ARCOS

28. The increase in shipments extended broadly across major classes of prescription opioids.

As shown in **Figure I.2**, the largest increase was for oxycodone, which includes Purdue

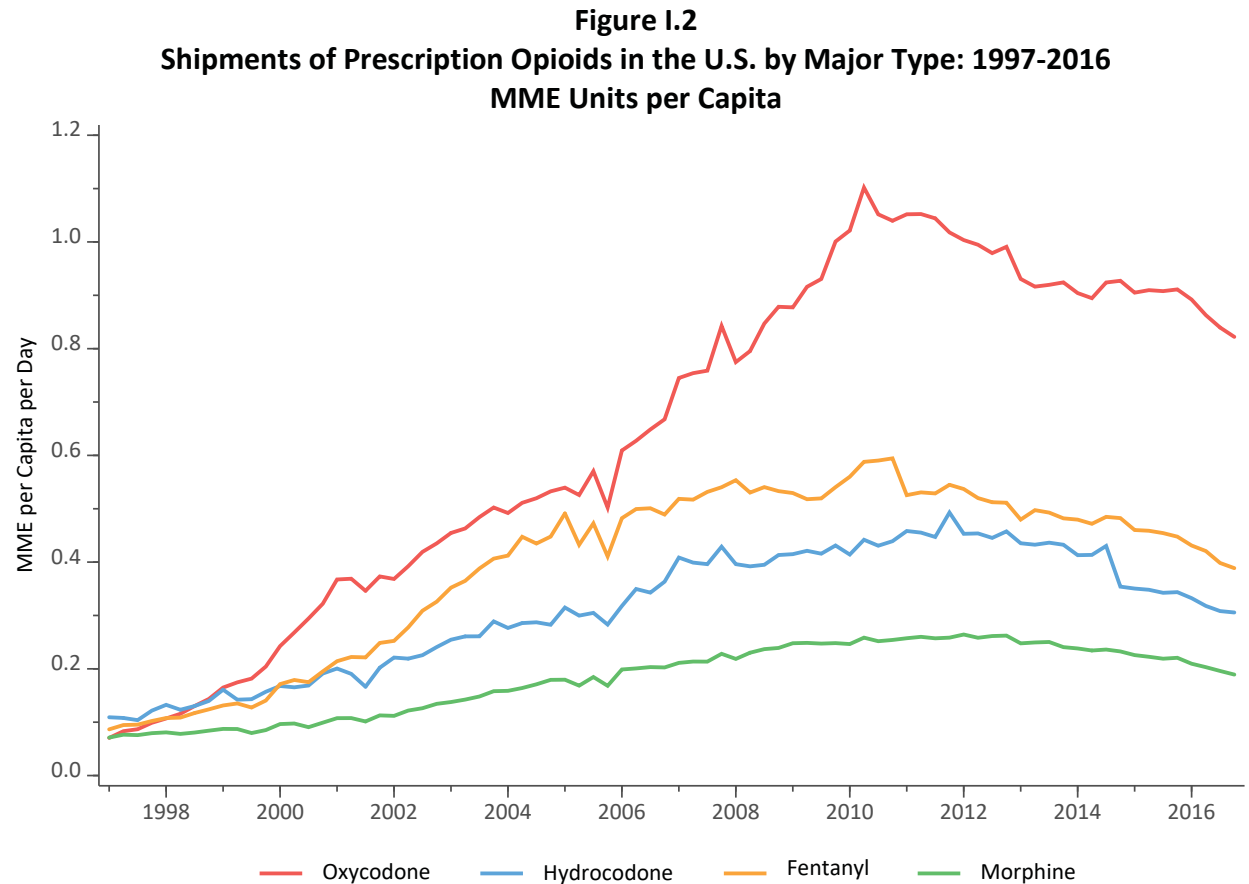
Pharmaceutical's OxyContin, for which shipments increased by 1,063 percent between Q1 1997

and Q4 2016. However, large increases in shipments over this period were also observed

³⁴ Milligram Morphine Equivalent (MME) is a measurement of the relative potency of opioids. It is calculated by multiplying an opioid dose, usually expressed in milligrams per day, by an opioid-specific conversion factor. The calculation of MME equivalents is discussed in the attached **Data Appendix**.

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among all major classes of opioids, including increases of 179 percent for hydrocodone, 348 percent for prescription fentanyl, and 165 percent for morphine.



Source: ARCOS

3. The Growth in Opioid Misuse: Post 1995

29. The rapid growth in shipments of prescription opioids was followed by a growth in opioid misuse and dependency. Measuring dependency properly is difficult, so a host of proxies are typically used. In the case of opioid addiction, they all tell a similar story of side-by-side growth in prescriptions and in opioid misuse and dependency.

30. The National Survey of Drug Use and Health (NSDUH), which is undertaken by the Substance Abuse and Mental Health Services Administration (SAMHSA) of the HHS, is a

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nationally representative household survey based on in-person interviews of roughly 70,000 individuals annually.³⁵ The NSDUH is the basis of some estimates of opioid misuse and dependency, specifically Opioid Misuse and Opioid Use Disorder (OUD) in the United States, both of which are defined based on a series of questions about social/interpersonal problems related to drug use, the frequency of hazardous use, legal problems related to use, the respondents' past attempts to quit or control use, the presence of withdrawal symptoms, time spent using, and other factors. The most recent data from NSDUH indicate that 4.1 percent of the adult population of the U.S. misused opioids in 2017, and that 0.8 percent of the population exhibited OUD.³⁶

31. It is generally acknowledged that NSDUH data underestimate OUD and the extent to which opioids are misused. There are several recognized sources of this downward bias. For example, the NSDUH sampling framework excludes certain categories of individuals who typically have high drug use, including people who are homeless, incarcerated, or otherwise institutionalized.³⁷ Further, it is recognized that survey respondents are hesitant to disclose use

³⁵ NSDUH, About the Survey, available at https://nsduhweb.rti.org/respweb/about_nsduh.html.

³⁶ Substance Abuse & Mental Health Data Archive's Public-use Data Analysis System (PDAS) (<https://pdas.samhsa.gov/#/>)

³⁷ See National Academies of Sciences, Engineering and Medicine, "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use," 2017 (National Academies of Sciences, Engineering and Medicine (2017)), p. 4-21. ("NSDUH [...] is a household-based sample that excludes institutionalized populations, homeless individuals, and others, and thus likely underestimates these outcomes.") See also, Report of The President's Commission on Combating Drug Addiction and the Opioid Crisis, November 1, 2017, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf, (President's Commission Opioid Report (2017)), pp. 24, 60. ("Past 30 day users of heroin [...] is probably an underestimate because NSDUH surveys households and does not capture heroin users in homeless shelters or transient populations with no fixed address, and the incarcerated.") See also, Pitt, Allison L., Keith Humphreys and Margaret L. Brandeau. Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic. *Am J Public Health*. 108 no. 10 (2018):1394-1400, Supplement, p. S4. ("The National Survey on Drug Use and Health (NSDUH) tends to underreport opioid use disorder due to omission of some key populations (e.g., homeless, incarcerated) that are known to have high rates of illicit drug use [...]").

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of illicit substances.³⁸ For example, a recent National Academies of Sciences, Engineering and Medicine report on pain management and the opioid epidemic notes:

Surveys, moreover, can underestimate drug consumption as a result of respondents' social desirability concerns or inability to recall, among other reasons. Even for alcohol, it has been found that survey self-reports account for only about half of the alcohol known to be sold based on tax records.³⁹

32. A 2014 study from the RAND Corporation also explains the difficulty of trying to measure the size of illicit drug activity:

The difficulty is not conceptual; at root, it is just counting. The problem is largely with the data. That statement is in no way a criticism of those who design and administer data systems upon which we rely. Rather, it is an inevitable consequence of trying to measure sales of something sold in hidden markets or consumption behavior that is both illegal and dominated by a relatively small number of heavy users.⁴⁰

33. The same study attempts to measure the extent to which the NSDUH underestimates heroin-related OUD and misuse. The authors estimate that the population of chronic users of heroin, defined as those who used heroin four or more times in the previous month, was approximately 1.5 million people in 2010, based on data from the since-discontinued Arrestee Drug Abuse Monitoring (ADAM) survey of recently incarcerated populations by the U.S. Department of Justice, among other sources.⁴¹ In contrast, estimates from NSDUH for 2010

³⁸ RAND Corporation, "What America's Users Spend on Illegal Drugs: 2000-2010," Prepared for US Office of National Drug Control Policy, February 2014 (RAND (2014)), p. 11, available at https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/ausid_results_report.pdf; National Academies of Sciences, Engineering and Medicine (2017), pp. 4-21 and 4-29 – 4-31; Keith Humphreys, "The federal government is systematically undercounting heroin users," *The Washington Post*, August 22, 2017, available at https://www.washingtonpost.com/news/wonk/wp/2017/08/22/the-federal-government-is-systematically-under-counting-heroin-users/?utm_term=.b0343c34bc6a.

³⁹ National Academies of Sciences, Engineering and Medicine (2017), p. 4-29.

⁴⁰ RAND (2014), p. 7.

⁴¹ See RAND (2014), Table S.2. for the estimate of 1.5 million chronic heroin users. These figures are also cited in the President's Commission Opioid Report (2017), p. 60.

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indicate that roughly 600,000 individuals used heroin in the prior year.⁴² However, even this comparison is likely to understate the extent of underreporting because the NSDUH data reflect estimates of chronic and occasional users of heroin while the RAND study attempts to identify only chronic users. Another recent study from Barocas et al. (2018) estimated the prevalence of OUD in Massachusetts.⁴³ This study found prevalence of OUD in Massachusetts in 2015 was 4.6 percent, more than four times the NSDUH estimate of 1.0 percent.⁴⁴

34. In addition to the issue of underreporting, a number of changes were made to the NSDUH questionnaire and data collection process starting with the 2015 survey that affected the data related to prescription drug use, misuse and abuse. As a result, measures of prescription OUD from NSDUH in 2015 and after are not comparable with prior data.⁴⁵

35. Given the limitations of the NSDUH survey, it is useful to consider alternative sources as measurement proxies for opioid dependence. One natural proxy is opioid-related mortality, which can be derived from data reported by the National Center for Health Statistics in the Multiple Cause of Death (MCOB) data files. These data are individual-specific and are based on death certificates issued by county officials and can report multiple causes of death.

⁴² President's Commission Opioid Report (2017), p. 60.

⁴³ Barocas, Joshua A., Laura F. White, Jianing Wang, Alexander Y. Walley, Marc R. LaRochelle, Dana Bernson, Thomas Land, Jake R. Morgan, Jeffrey H. Samet and Benjamin P. Linas. "Estimated Prevalence of Opioid Use Disorder in Massachusetts, 2011–2015: A Capture–Recapture Analysis." *AJPH Open Themed Research* Vol. 108 no. 12 (Dec 2018): 1675-1681.

⁴⁴ Substance Abuse & Mental Health Data Archive's Restricted-use Data Analysis System (RDAS) (<https://rdas.samhsa.gov/#/>)

⁴⁵ NSDUH, "2015 National Survey on Drug Use and Health - Summary of the Effects of the 2015 NSDUH Questionnaire Redesign: Implications for Data Users," June 2016, pp. 1, 4-6.

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36. As discussed in the attached **Data Appendix**, public MCOD data that identify opioid-related mortality are available from 1968 through 2017 but are subject to limitations with respect to the scope of detail available on geography and type of opioids that contributed to deaths.⁴⁶ Some analysis in this report is based on data from 404 counties identified in the MCOD data that have consistently available data over the period of 1993 to 2016 (“Large Counties”), including the Bellwether counties. For confidentiality reasons, counties with population less than roughly 100,000 are not identified in the MCOD data until 2005, although larger counties are identified throughout the time period.

37. The MCOD data, like the NSDUH data, contain some important limitations:

- First, analysis of changes over time in overdose rates by reason for mortality is complicated by the revision in 1999 of the International Classification of Diseases (ICD) codes used to classify causes of death in MCOD.
- Second, pre-1999 MCOD data do not identify the type of opioid(s) that contributed to a death (e.g., prescription opioids, heroin, fentanyl, etc.); they instead only identify whether an overdose was opioid related.
- Third, some deaths identified as drug overdoses do not identify the drugs involved in the death, opioid or otherwise.
- Fourth, in 1999 and later, when opioids are identified as a source of an overdose death, the data do not always report the type of opioid involved.

⁴⁶ Limited MCOD data for 2017 recently become available through CDC’s WONDER data retrieval system. Where possible, I have incorporated these data into my analysis.

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- Finally, death records are typically generated by county coroners and reporting practices may differ across areas and may change over time due to changes drug testing procedures and other factors.

38. As explained in the attached **Data Appendix**, the analysis of MCODE presented here attempts to correct for many of these limitations of the MCODE data. Specifically, the analysis adjusts for the revision in the ICD codes based on compatibility ratios identified in the epidemiological literature for differences in the definitions of drug-related deaths. In addition, the analysis applies an approach developed by Christopher J. Ruhm (2018) to adjust mortality rates to account for overdose death records that do not specify the drug involved, and to account for opioid overdoses that do not identify the detailed type of opioid.⁴⁷ My analysis also adjusts for changes in the age composition of the population over time.

39. Much of my analysis categorizes opioid-related drug overdoses into one of three categories, which account for the fact that multiple opioids are often identified as a cause of death for individual victims:

- Prescription Opioid overdoses only (e.g., no heroin or fentanyl was identified);
- Heroin overdoses (e.g., any overdose in which heroin is identified, but not fentanyl);
- Fentanyl overdoses (e.g., any overdose in which fentanyl was identified).

For simplicity, several charts below are based on illicit opioid overdoses, which includes any overdoses that involve either heroin or fentanyl. In order to maintain consistency with analysis presented below that requires county data, much of the analysis presented in this report is

⁴⁷ Ruhm, Christopher J., "Corrected US opioid-involved drug poisoning deaths and mortality rates, 1999–2015," *Addiction* 113 (2018): 1339-1344 (Ruhm (2018)).

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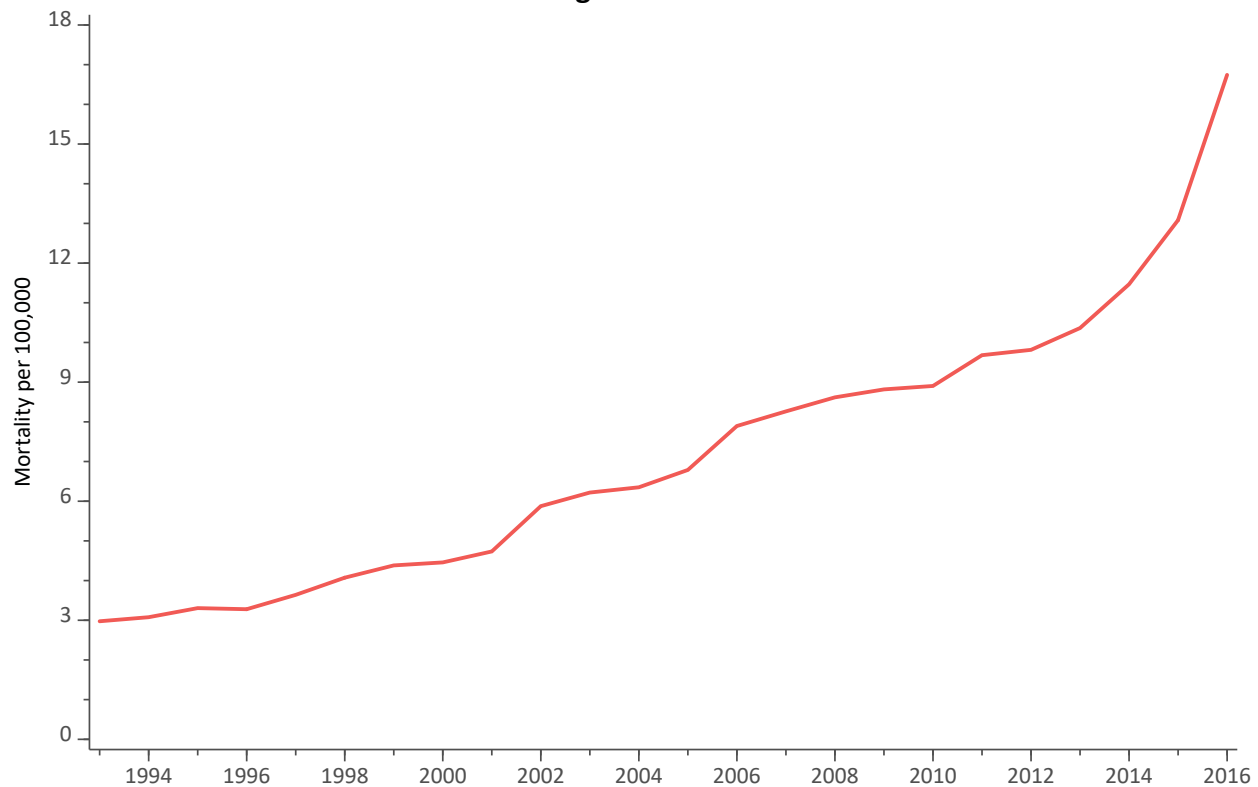
based on mortality rates from large counties, as defined above. These counties account for 69 percent of the U.S. population and, as shown in the attached **Data Appendix**, the trend in opioid-related mortality in these areas is very similar to those observed for the U.S. as a whole.⁴⁸

40. **Figure I.3** reports the opioid-related mortality rate (expressed as deaths per 100,000 adults) in large counties of the United States from 1993 to 2016. This figure shows that the (adjusted) rate increased by a factor of more than 4.6 since the early 1990s. I rely on opioid-related mortality as an indicator of the extent of opioid misuse. Like any proxy, opioid-related mortality is an imperfect proxy for opioid misuse. But these data nonetheless illustrate the general trend over time in opioid misuse and are used as a proxy for opioid-related harm in the Cutler Report.

⁴⁸ The simple correlation between the national opioid-related mortality rate and the total rate in the large county sample is 0.996, indicating that changes over time in the national data closely mirror changes over time in the large county data.

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Figure I.3
Opioid Overdose Mortality Rate: 1993-2016
Large Counties



Source: NCHS Mortality Data and Census Data

B. Initial Responses to the Crisis

41. Over time, policymakers, federal and state law enforcement, and the public more generally began to recognize the emergence of a crisis of opioid dependence. By the late 2000s, many states had started to implement programs and laws to try to address it, including Prescription Drug Monitoring Programs (PDMPs), opioid prescribing cap laws, and laws designed to regulate the activities of pain clinics.⁴⁹ Meanwhile, a variety of legal actions were undertaken by federal and state law enforcement officials resulting in both settlements and

⁴⁹ McGinty, Emma E., Elizabeth A. Stuart, G. Caleb Alexander, Colleen L. Barry, Mark C. Bicket and Lainie Rutkow. "Protocol: mixed-methods study to evaluate implementation, enforcement and outcomes of U.S. state laws intended to curb high-risk opioid prescribing." *Implementation Science* 13 (2018) (McGinty et al. (2018)), pp. 2, 4.

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criminal convictions. This section provides a brief overview of these initial responses to the crisis.

1. The Growth of PDMPs and Related Programs

42. PDMP programs are designed, among other goals, to reduce excessive prescriptions of opioids by doctors, as well as patient behavior, such as “doctor shopping,” that is intended to evade limits on physician-prescribed opioids. PDMPs typically place enrollment and reporting requirements on physicians and pharmacies; collect data from pharmacies on prescriptions of controlled substances; give authorized users access to information about a patient’s controlled substance prescription history, typically through an electronic database; and require providers to check the state’s PDMP before prescribing opioids to an individual.⁵⁰ PDMPs were initiated at different times in different states, and different provisions were phased in over time within each state. Other laws are designed to prevent rogue clinics, or “pill mills” from excessive prescribing opioids and to subject pain management clinics to increased regulatory oversight.⁵¹ The scope of these programs and laws, and the obligations they place on industry participants, varied substantially across states, and many requirements have been only become effective in the last few years.⁵²

43. The effectiveness of PDMPs has been widely analyzed and the results of the studies indicate that PDMPs have met with mixed success to date. For example, a 2017 review of some

⁵⁰ President’s Commission Opioid Report (2017), p. 53; PDMP Center of Excellence at Brandeis University, “Briefing on PDMP Effectiveness,” September 2014, available at http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf (PDMP Center of Excellence (2014)), p. 3; McGinty et al. (2018).

⁵¹ McGinty et al. (2018).

⁵² McGinty et al. (2018).

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of these studies concluded: “Although PDMP implementation has been initiated across the United States, little consistent evidence has yet emerged to demonstrate PDMPs’ impact on outcomes of greatest importance, whether more proximal targets such as prescribing behavior or distal outcomes such as opioid misuse, diversion, morbidity and mortality.”⁵³ The CDC’s website, however, presents a more favorable evaluation, highlighting that “[s]tate-level policies that enhance prescription drug monitoring programs (PDMPs) or regulate pain clinics have shown some promising results.”⁵⁴ The CDC highlights positive outcomes between 2010 and 2015 in various states, including reductions in MME prescribed per capita, Oxycodone deaths and “doctor shopping”.⁵⁵

2. Legal Actions

44. As early as 2007-08, law enforcement officials brought actions claiming that manufacturers misrepresented the addictive properties of opioids and that distributors failed to meet their obligations to monitor and report suspicious patterns of shipments. For example:

- In 2007, Purdue settled criminal and civil charges for misbranding OxyContin with the intent to defraud and mislead the public about its addictive qualities. Purdue agreed to pay the United States \$635 million.⁵⁶ Three executives pleaded guilty to misbranding the drug.⁵⁷

⁵³ Finley, Erin P., Ashley Garcia, Kristen Rosen, Don McGeary, Mary Jo Pugh and Jennifer Sharpe Potter. “Evaluating the impact of prescription drug monitoring program implementation: a scoping review.” *BMC Health Services Research* 17 (2017). DOI 10.1186/s12913-017-2354-5.

⁵⁴ <https://www.cdc.gov/drugoverdose/policy/successes.html>.

⁵⁵ <https://www.cdc.gov/drugoverdose/policy/successes.html>.

⁵⁶ Cuyahoga Complaint, ¶43. Heather Won Tesoriero, “OxyContin Maker Pleads Guilty --- Purdue Frederick to Pay \$634.5 Million Settlement For Hiding Addiction Risk,” *The Wall Street Journal*, May 11, 2007.

⁵⁷ Heather Won Tesoriero, “OxyContin Maker Pleads Guilty --- Purdue Frederick to Pay \$634.5 Million Settlement For Hiding Addiction Risk,” *The Wall Street Journal*, May 11, 2007.

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- Also in 2007, Purdue agreed to pay \$19.5 million to 26 states and the District of Columbia to settle complaints that it encouraged physicians to overprescribe its painkiller OxyContin.⁵⁸
- In 2008, McKesson paid \$13 million to settle allegations that it violated federal reporting provisions relating to its handling of certain prescription medications regulated by the DEA. McKesson was accused of failing to report excessive sales of their products to pharmacies filling illegal online prescriptions for hydrocodone (contained in drugs such as Vicodin).⁵⁹
- Also in 2008, Cardinal Health agreed to pay \$34 million to settle claims that it failed to report suspicious sales of controlled substances to the DEA.⁶⁰

45. Before, during and after this period, DOJ and the DEA took action seeking to shut down and prosecute “pill mills” that distributed opioids. For example, between 2003 and 2017 the DEA convicted more than 250 doctors for their participation in various prescription opioid related offenses, including trafficking in illegal drugs, unlawful dispensing of a Schedule II controlled substance and felony murder, among other charges.⁶¹ And between 2007 and 2017 DOJ charged more than 150 medical professionals, including doctors, nurses and pharmacists,

⁵⁸ Associated Press, “Painkiller's Maker Settles Complaint,” *The New York Times*, May 9, 2007.

⁵⁹ DOJ Press Release, “McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications,” May 2, 2008, available at <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

⁶⁰ US States Attorney’s Office Colorado, “Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims That it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances,” October 2, 2008, available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

⁶¹ Data compiled by counsel related to criminal cases against doctors brought by DEA since 2003: <https://apps.deadiversion.usdoj.gov/CasesAgainstDoctors/spring/main?execution=e1s1>.

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for their participation in “pill mills” or in the writing or filling of fraudulent opioid prescriptions.⁶²

C. The Emergence of the Illicit Opioid Crisis

1. The Growth in Heroin Abuse after 2010

46. Beginning around 2010, increased enforcement actions by DEA and DOJ, criminal actions and litigation, the growth of state PDMP laws, and increased awareness of addiction risks associated with prescription opioids contributed to a reduction in aggregate shipments of prescription opioids after more than 20 years of rapid growth. Around the same time Purdue Pharmaceuticals launched its abuse deterrent formulation of OxyContin that purported to make it more difficult for people that were opioid dependent to use it to meet their addiction-related needs. Before 2010, the time-release aspect of OxyContin could be evaded simply by crushing pills, which facilitated abuse by individuals that were dependent on opioids.⁶³ But reformulation by Purdue and other manufacturers of the product attempted to make that simple path to abusing OxyContin more difficult.⁶⁴

47. While opioid death rates continued to climb as demonstrated in Figure I.3, all of these factors contributed to decline in prescription opioid shipments. For example, the FDA pointed to these confounding factors in their review of the efficacy of Purdue’s ADF OxyContin citing to “pill-mill legislation and law enforcement crackdowns in Florida and other states, the

⁶² Based on a search of DOJ press releases during this period.

⁶³ Abby Goodnough and Katie Zezima, “Drug Is Harder to Abuse, but Users Persevere,” *The New York Times*, June 15, 2011, available at <https://www.nytimes.com/2011/06/16/health/16oxy.html>.

⁶⁴ Abby Goodnough and Katie Zezima, “Drug Is Harder to Abuse, but Users Persevere,” *The New York Times*, June 15, 2011, available at <https://www.nytimes.com/2011/06/16/health/16oxy.html>. Even after the reformulation, OxyContin could still be abused orally, and it is not clear that the reformulation reduced abuse, as discussed below.

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development and implementation of prescription drug monitoring programs, changes in state-level requirements for prescribing and dispensing opioids, other federal interventions such as the extended-release and long-acting (ER/LA) opioid REMS, and the removal of generic extended-release oxycodone products from the market.”⁶⁵

48. While Purdue’s ADF was approved by the FDA, this does not imply that it was necessarily effective in limiting abuse. In fact, the same FDA studies referenced above suggest that there was not a meaningful or sustained reduction in overall opioid abuse attributable to reformulation.⁶⁶ Instead, my analysis, consistent with studies from the FDA and others as well as economic literature summarized in more detail below, indicates that the reformulation was one of many other causes that led to increased illicit heroin use. The FDA study further indicates that there were a variety of other factors that led to increased heroin use. For instance, the study states that “[a]vailability of heroin, for example, may provide an avenue for prescription opioid abusers to switch in the presence of law enforcement restrictions.”⁶⁷ In addition, Cuyahoga County has acknowledged that “[a]buse-deterrent formulations of medications [...] may have inadvertently shifted abuse towards heroin.”⁶⁸

49. At the same time these events were occurring, there was a 26 percent decline in shipments of prescription opioids measured on an MME basis from Q2 2010 to Q4 2016.

⁶⁵ PPLPC005000211723, at 1728.

⁶⁶ *Id.* at 2105-06.

⁶⁷ *Id.* at 1823.

⁶⁸ <http://www.ccbh.net/opiates/>

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However, this masks the fact that shipments of some types of opioids continued to increase after 2010, including certain ostensibly non-abuse deterrent ones.

50. Reduced availability of prescription opioids generated demand for illicit opioids as some users turned to heroin. As early as 2004, Ohio's Substance Abuse Monitoring Network (OSAM) noted that "focus group participants reported the continued increase in heroin use in the Summit-Stark area. All groups reported new heroin addicts emerging as they are finding heroin to be less expensive than OxyContin."⁶⁹ In 2008, OSAM again noted that "[m]any users abuse pharmaceutical opioids such as OxyContin (oxycodone, extended-release) and then switch to heroin use."⁷⁰

51. However, the substitution of illicit opioids for prescription opioids expanded dramatically starting around 2010, closely coinciding with the declines in shipments associated with increased legal enforcement, increased awareness of the potential for abuse, and the launch of abuse deterrent formulations. Some academic studies (discussed further below) stress the role of the reformulation of OxyContin, but this was just one of several factors contributing to the shift of demand from prescription opioids to illicit opioids. Indeed, abuse deterrent formulations did not eliminate the risk of addiction or abuse, and declines in shipments for an array of prescription opioids over the same period contributed to the demand for illicit opioids. Effectively, a variety of elements of public policy and the legal environment raised the relative costs of using prescription opioids, leading those individuals who had become addicted to prescription opioids to turn to substitute products to satisfy that addiction.

⁶⁹ OSAM, "Surveillance of Drug Abuse Trends in the State of Ohio," January – June 2004, p. 4-5.

⁷⁰ OSAM, "Surveillance of Drug Abuse Trends in the State of Ohio," January – June 2008, p. 9.

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As discussed further below, epidemiologists estimate that fully 75 percent of those who reported their first regular opioid use in the 2000s reported that their first regular opioid use was a prescription drug.⁷¹

52. It is well known that heroin can be a much more dangerous method for satisfying addiction-related needs than prescription opioids. This is due in part to high variability in the extent of adulteration and potency in illegal opioids. As a result, the increased demand for heroin after 2010 substantially increased the risk of death faced by people dependent on opioids. Available data establish that illicit opioid mortality began to increase sharply in 2010. As shown in **Figure I.4**, the increase in deaths involving heroin coincides with the general decline in shipments of prescription opioids and related events after 2010. As discussed further below, other studies establish that the transition from prescription opioids is related to increased demand for illegal opioids and increased opioid-related mortality after 2010. For example, Evans et al. (2019) notes that “[w]hen we combine heroin and opioid deaths together, we find no evidence that total heroin and opioid deaths fell at all after the reformulation—there appears to have been one-for-one substitution of heroin deaths for opioid deaths. Thus, it appears that the purpose for the abuse-deterrent reformulation of OxyContin was completely undone by changes in consumer behavior.”⁷²

⁷¹ Cicero, Theodore J., Matthew S. Ellis, Hilary L. Surratt, and Steven P. Kurtz. “The changing face of heroin use in the United States: A retrospective analysis of the past 50 years.” *JAMA Psychiatry* 71 (2014): 821-826 (Cicero et al (2014)).

⁷² Evans, William N., Ethan Lieber, Patrick Power. “How the Reformulation of Oxycontin Ignited the Heroin Epidemic.” *Review of Economics and Statistics* 101 no. 1 (2019): 1-15 (Evans et al. (2019)), at p. 2.

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Figure I.4
Heroin Overdose Mortality Rate: 1999-2016



Note: Mortality rate is the annual rate shown monthly.
 Source: NCHS Mortality Data and Census Data

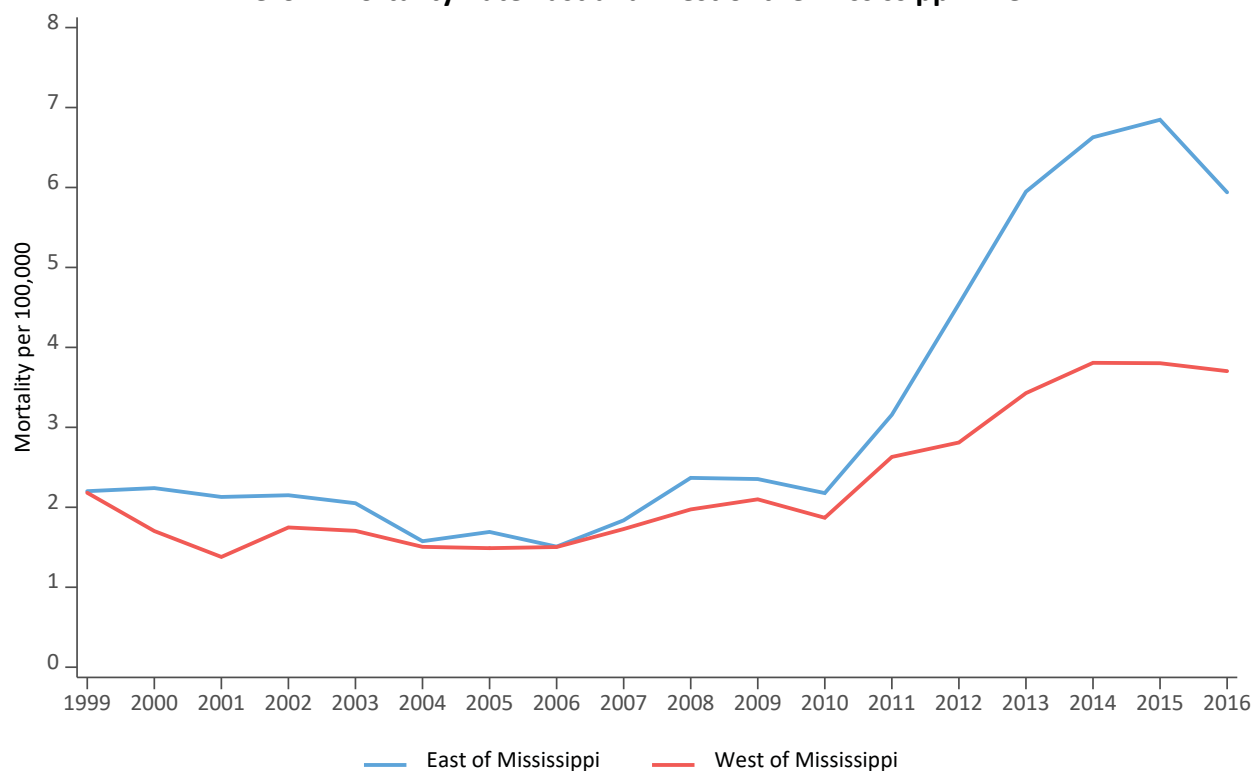
53. However, the various forms of heroin and demand and supply conditions in the heroin market vary widely across areas of the country. As a result, the increased demand for illicit opioids resulting from the reduction in shipments of prescription opioids operated differently in different areas. As explained further below, market conditions in Ohio, including Cuyahoga and Summit Counties, made it especially vulnerable to illicit opioids after 2010.

54. Since at least the 1990s, the market for heroin in the U.S. has been divided geographically, with states east of the Mississippi dominated by powder heroin and western

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states dominated by black tar heroin.⁷³ Powder heroin proved to be a closer substitute for prescription opioids than black tar heroin. Observers attribute this to the fact that “white powder heroin looks much like a crushed pain pill, making it comparatively easy to switch from one to the other.”⁷⁴ The rapid increase in heroin mortality in eastern states compared to those in the west after 2010 is consistent with these observations, as displayed in **Figure I.5**.

Figure I.5
Heroin Mortality Rate East and West of the Mississippi River



Source: NCHS Mortality Data

⁷³ US Department of Justice Drug Enforcement Administration, “2017 National Drug Threat Assessment,” available at https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf, p. 48. Black tar heroin is a dark, rock-like form of heroin that is often produced in Mexico and sold in areas west of the Mississippi River. See <https://www.drugrehab.com/addiction/drugs/heroin/black-tar/>

⁷⁴ *The Economist*, “Inside the opioid epidemic – A selective scourge,” May 11, 2017, available at <https://www.economist.com/united-states/2017/05/11/inside-the-opioid-epidemic>. See also US Department of Justice Drug Enforcement Administration, “2016 National Drug Threat Assessment,” available at https://www.dea.gov/sites/default/files/2018-07/DIR-001-17_2016_NDTA_Summary.pdf, p. 49.

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2. The Emergence of Fentanyl: Post-2013

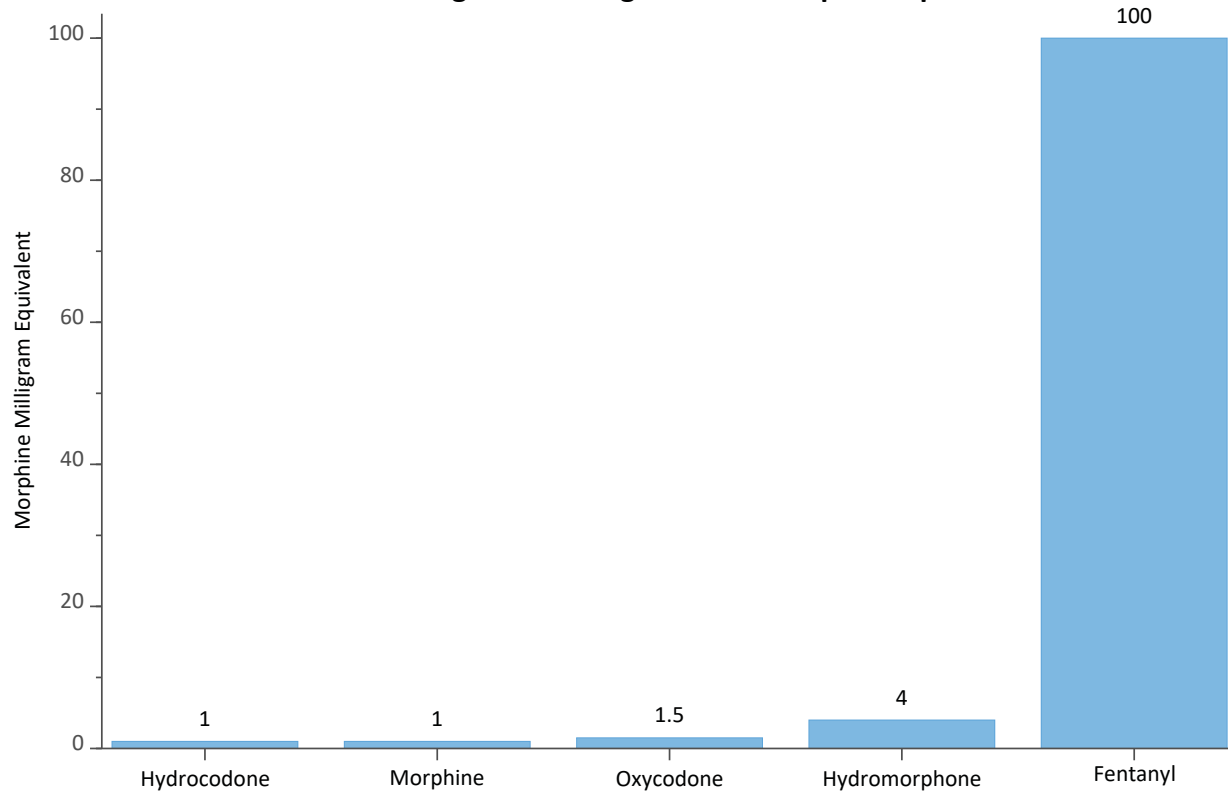
55. Illicit opioid mortality accelerated again after 2013 as drug traffickers started to incorporate fentanyl as a lower-cost alternative to heroin. Fentanyl, which has long been available on a prescription basis, entered the illicit drug market through illegal imports, mainly from China and Mexico.⁷⁵ In illicit uses, fentanyl is often mixed with heroin and other drugs to lower the cost to drug dealers and to increase the high to users. Fentanyl is also widely used in the manufacture of counterfeit prescription opioids.⁷⁶ Fentanyl contains high concentrations of opioids – 1 mg of fentanyl is equivalent in potency to 100 milligrams of morphine, while 1 mg of OxyContin is equivalent to 1.5 milligrams of morphine – and as a result, small errors in dosage or quality due to improper mixing and preparation results in high overdose risks. **Figure I.6** displays the relative strength of 1 milligram of opioids across various forms.

⁷⁵ DEA Intelligence Brief, “Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, DEA-DCT-DIB-021-16,” July 2016, available at https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf, p. 7.

⁷⁶ Id.

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Figure I.6
Relative Strength of 1 Milligram of Prescription Opioids



Source: Centers for Medicare & Medicaid Services

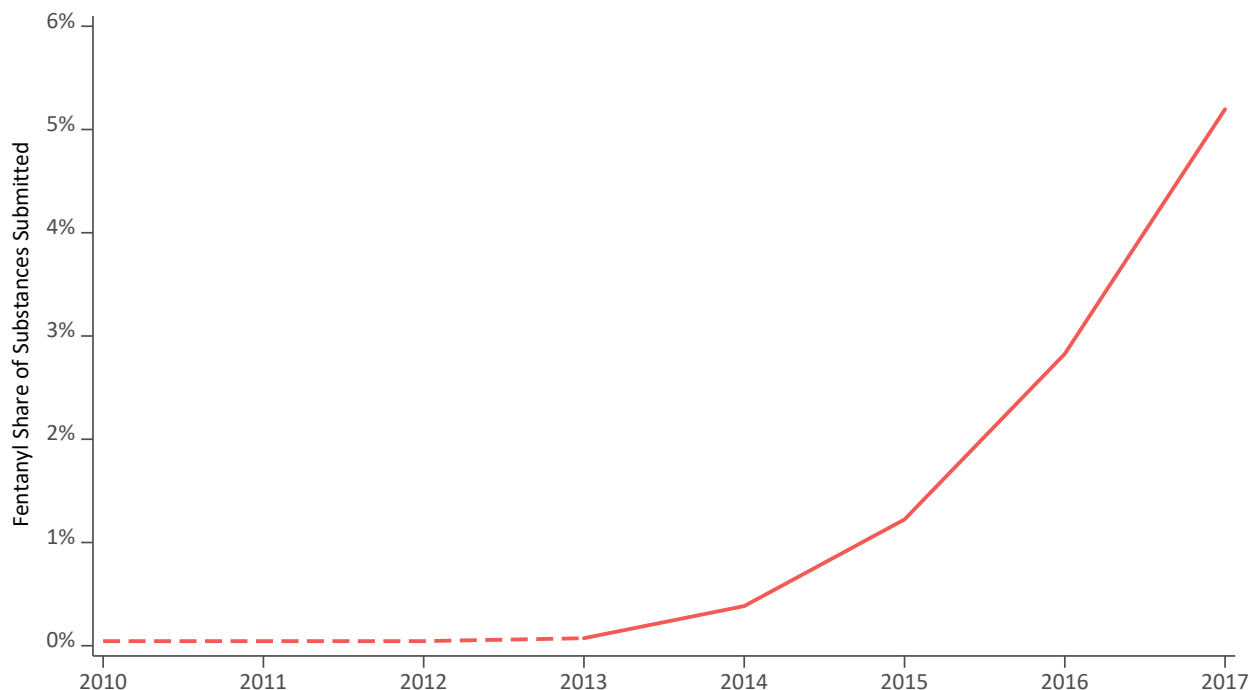
56. As shown in **Figure I.7**, the number of drug confiscations in which fentanyl has been identified has skyrocketed in recent years. The DEA's National Forensic Laboratory Information System (NFLIS) reports the identification results of drug samples confiscated by law enforcement that were submitted to and analyzed by participating federal, state and local forensic laboratories for testing.⁷⁷ In total, the share of drug confiscations by law enforcement that involved fentanyl increased from 0.1 percent in 2013 to 5.2 percent in 2017. This

⁷⁷ National Forensic Laboratory Information System: Questions and Answers (Q&A), available at <https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLISPublicDataQA.pdf>

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corresponds to an increase in the number of fentanyl confiscations recorded in NFLIS data from 1,042 in 2013 to 77,057 in 2017.⁷⁸

Figure I.7
Share of Drug Confiscations Identified in NFLIS Involving Fentanyl
United States



Notes: (1) Share reflects fentanyl substances included in top 60 NFLIS substances identified divided by total identified top 60 substances. (2) Fentanyl substances include 4-Fluoroisobutyl fentanyl, Acetyl fentanyl, Acryl fentanyl, Carfentanyl, Cyclopropyl fentanyl, Fentanyl, and Furanyl fentanyl. (3) Fentanyl substances are not in top 60 substances in 2011 and 2012.

Source: U.S. Drug Enforcement Administration, Diversion Control Division.

57. The growth in fentanyl-related mortality has continued uninterrupted since 2013. As shown in **Figure I.8**, mortality from prescription fentanyl followed no discernable trend prior to

⁷⁸ NFLIS data. The growth in the number of confiscations involving fentanyl is modestly influenced by an increase in the number of laboratories reporting to NFLIS over this period. Between 2013 and 2017 the number of laboratories reporting to NFLIS increased from 272 to 278, and covered more than 90 percent of U.S. State and local drug analysis cases throughout this period. (NFLIS Annual Reports for 2013, 2014, 2015, 2016 and 2017, available at <https://www.nflis.deadiversion.usdoj.gov/reports.aspx>, p. 4.) See also CDC maps on fentanyl seizures by year and state demonstrating the rapid increase in fentanyl seizures (<https://www.cdc.gov/drugoverdose/data/fentanyl-le-reports.html>).

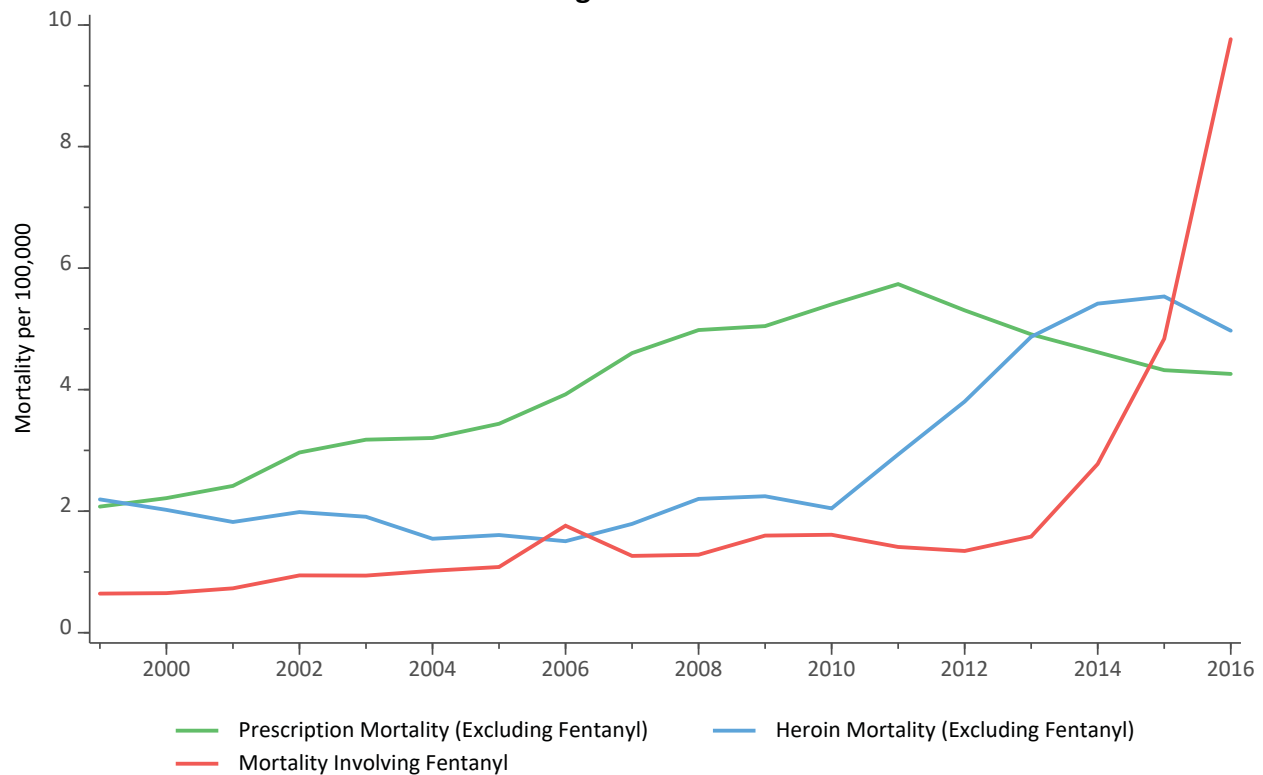
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2013, except for a brief outbreak of illicit use in 2006, and fentanyl-related mortality did not increase in 2011 through 2013 as heroin mortality rose.⁷⁹ In 2010, fentanyl was identified in 14.6 percent of all opioid-related deaths; by 2016, that figure rose to more than 49 percent of all opioid-related deaths. As set forth in more detail below, the rise in opioid-related deaths involving fentanyl is particularly evident in Bellwether jurisdictions. And as this figure indicates, the increase in mortality from illicit opioids (including deaths involving either heroin or fentanyl) has far more than offset the decline in prescription opioid mortality since 2010. To be clear, however, the below figure demonstrates that death rates from prescription opioid mortality remain high even after 2010.

⁷⁹ The 2006 event was traced to a single lab in Mexico which was shut down. (US Department of Justice National Drug Intelligence Center, "National Drug Threat Assessment 2008," available at <https://www.justice.gov/archive/ndic/pubs25/25921/25921p.pdf>, p. iii)

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Figure I.8
Prescription and Illicit Opioid Mortality Rate: 1999-2016
Large Counties



Source: NCHS Mortality Data

58. Fentanyl is a low-cost and high potency alternative to heroin used by drug dealers that is blended with heroin or otherwise sold as heroin. In 2017, the DEA estimated that the cost to drug traffickers of fentanyl (on a per MME basis) is roughly one-twentieth of that for heroin. More specifically, the DEA estimates that drug trafficking organizations face costs of \$5,000 - \$7,000 per kg for heroin (from Columbia) compared to fentanyl costs of \$3,500 - \$5,000 per kg. But one kg of fentanyl yields 16-24 kg of final product.⁸⁰ As a result, the enormously high margins that dealers earn from fentanyl has led many to substitute fentanyl for heroin. As the

⁸⁰ US Department of Justice Drug Enforcement Agency, "2017 National Drug Threat Assessment," available at https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf, p. 62.

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DEA notes, “fentanyl originally entered illicit drug markets through heroin; fentanyl in powder form is used as an adulterant and mixed into heroin, oftentimes without heroin users knowing.”⁸¹ The DEA further notes that “it is increasingly more common for fentanyl to be mixed with adulterants and diluents and sold as heroin, with no heroin present in the product.”⁸²

59. The low cost of fentanyl also led dealers to use it to create counterfeit OxyContin and other prescription opioids. As the DEA notes, “The profitability of fentanyls provides a strong motive for traffickers to produce counterfeit prescription pills to expand the current user base. Traffickers can typically purchase a kilogram of fentanyl powder for a few thousand dollars from a Chinese supplier, transform it into hundreds of thousands of pills, and sell the counterfeit pills for millions of dollars in profit.”⁸³

60. When sold by drug dealers to end users, fentanyl is typically mislabeled and represented as heroin or prescription opioids. As the DEA notes, “fentanyl in these forms looks like heroin, is packaged in the same baggies or wax envelopes as heroin, and displays similar stamps or

⁸¹ US Department of Justice Drug Enforcement Agency, “2017 National Drug Threat Assessment,” available at https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf, p. 59.

⁸² US Department of Justice Drug Enforcement Agency, “2017 National Drug Threat Assessment,” available at https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf, p. 59.

⁸³ DEA Intelligence Brief, “Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, DEA-DCT-DIB-021-15,” July 2016, available at https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf, p. 8.

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brands as heroin. While many heroin users have no desire to use fentanyl, some do seek it out because of its potency.”⁸⁴

61. This mislabeling indicates that fentanyl is (generally) not a product characteristic preferred by consumers, and that its emergence is not driven by consumers’ demand for a new type of drug. Instead, as noted, fentanyl is typically sold as heroin when mixed with heroin or neutral substances; when pressed into pills it is sold as prescription opioids. Users today recognize the dangers associated with fentanyl and many say they are willing to use test strips to identify its presence.⁸⁵ As this indicates, the emergence of fentanyl was driven by drug traffickers’ desire to increase margins on and increase the sales of heroin. That is, the emergence and growth of fentanyl reflects an extension of the post-2010 growth in the illicit opioid marketplace, not a new illicit drug whose growth was unrelated to the already existing illicit opioid epidemic.

62. Because it is a powder, it is easier to substitute fentanyl for powdered heroin than for black tar heroin, which is a hard and sticky substance shipped as bricks.⁸⁶ As a result, fentanyl emerged in areas in which powdered heroin was prevalent -- its emergence after 2013 was

⁸⁴ US Department of Justice Drug Enforcement Agency, “2017 National Drug Threat Assessment,” available at https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf, p. 59.

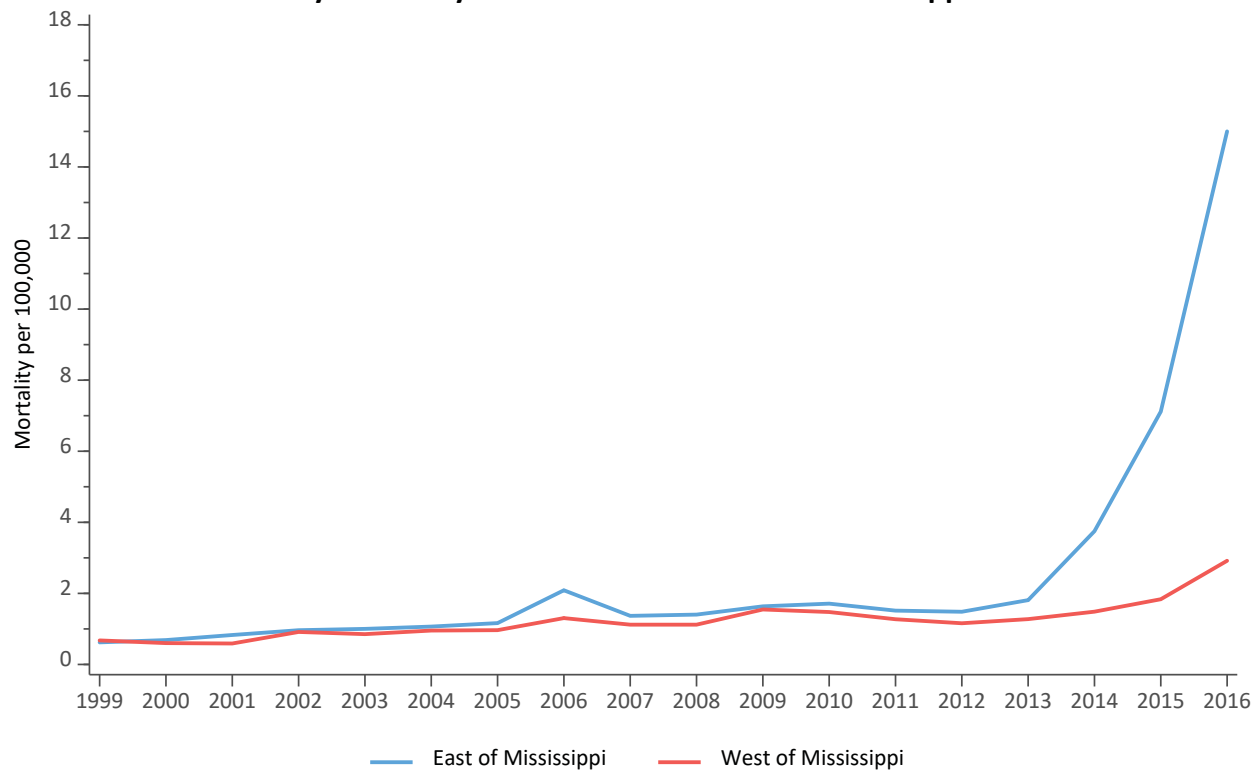
⁸⁵ “The vast majority (n = 86, 92%) of participants wanted to know if there was fentanyl in their drug supply prior to their use.” “Young adults have experienced the greatest increases in fentanyl overdose mortality as heroin and counterfeit pill use has surged over the last decade [17, 18].” (Krieger, Maxwell S., Jesse L. Yediank, Jane A. Buxton, Mark Lysyshyn, Edward Bernstein, Josiah D. Rich, Traci C. Green, Scott E. Hadland and Brandon D. L. Marshall. “High willingness to use rapid fentanyl test strips among young adults who use drugs.” *Harm Reduction Journal* 15 (2018), available at <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0213-2>)

⁸⁶ “A ready explanation is that illicit fentanyls come in powder form and thus more easily adulterate powder heroin than solid, i.e., ‘black tar’, heroin.” (Ciccarone, Daniel. “Fentanyl in the US heroin supply: a rapidly changing risk environment.” *International Journal of Drug Policy* 46 (2017): 107-111.)

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even more highly concentrated in the eastern U.S., where powdered heroin was more prevalent, than in the western U.S., where black tar heroin was more prevalent. (See **Figure I.9**). Fentanyl mortality also emerged most strongly in counties that had already been hard hit by increases in heroin mortality after 2010. More specifically, the correlation between change in heroin mortality between 2010-13 and fentanyl mortality in 2016 in the large county sample is 0.57. The correlation is large and significant, but also indicates that (unobservable) local supply conditions play an important role in the emergence of heroin and fentanyl.

Figure I.9
Fentanyl Mortality Rate East and West of the Mississippi River



Source: NCHS Mortality Data

63. Thus, through a dramatic sequence of events, the opioid epidemic developed from the overuse, misuse and diversion of prescription opioids to one involving both prescription opioids

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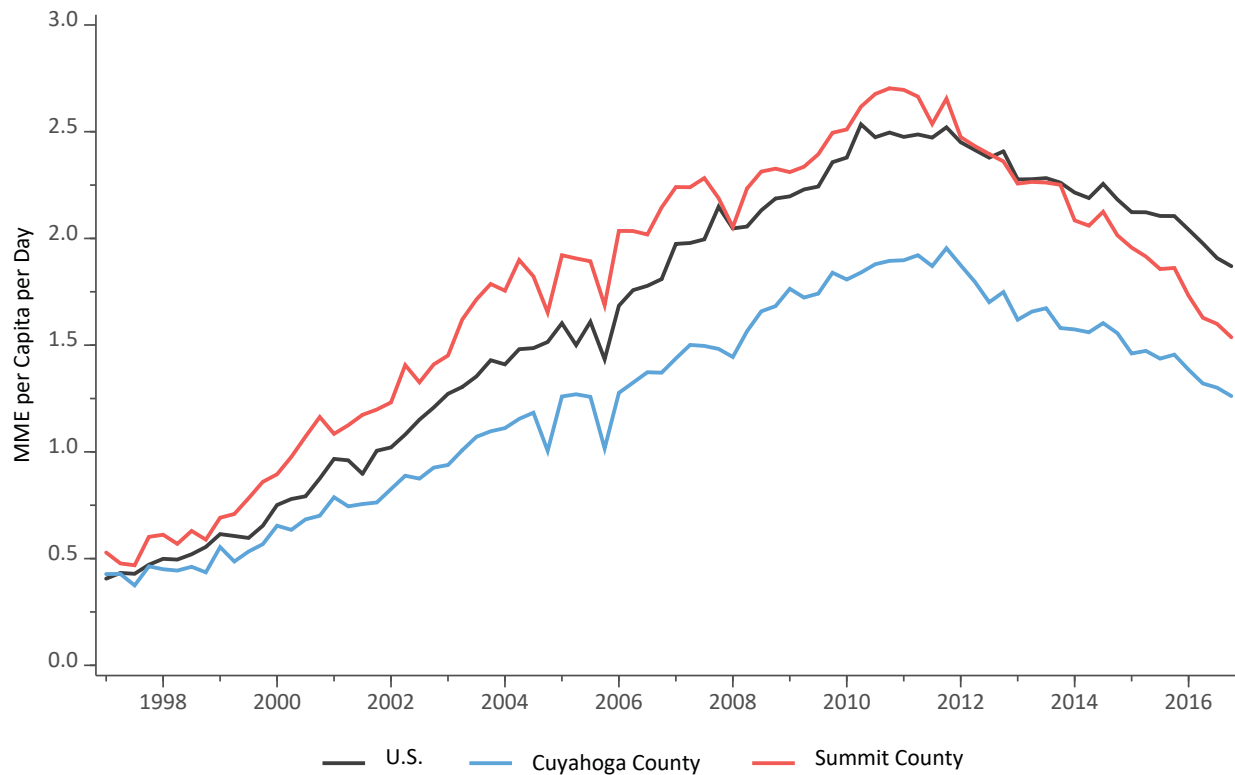
and, with even more grave consequences, illicit opioids. I provide further evidence below that the illicit opioid crisis would not have occurred in the absence of defendants' shipments of prescription opioids. Given this overlap in the emergence of heroin and fentanyl related mortality in the post-2010 period, much of the discussion below focuses on the distinction between prescription and illicit mortality, which is defined to include deaths involving either heroin or fentanyl.

D. The Opioid Crisis in Cuyahoga and Summit Counties

64. The history of the opioid epidemic in the Bellwether communities was generally similar to that observed nationwide through 2010, but Cuyahoga and Summit Counties, and other parts of Ohio and nearby states, have been particularly hard hit by the illicit crisis post-2010. As **Figure I.10** indicates, per capita shipments of prescription opioids to Summit County between 1997 and 2016 were on average modestly higher than the national average while shipments to Cuyahoga County were below average, and neither was a significant outlier among large counties. In both areas, shipments followed the trajectory observed in the national data, growing steadily through 2010, and then starting a steady decline that continued through 2016.

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Figure I.10
Shipments of Prescription Opioids: 1997-2016
Bellwether Counties and U.S. Total



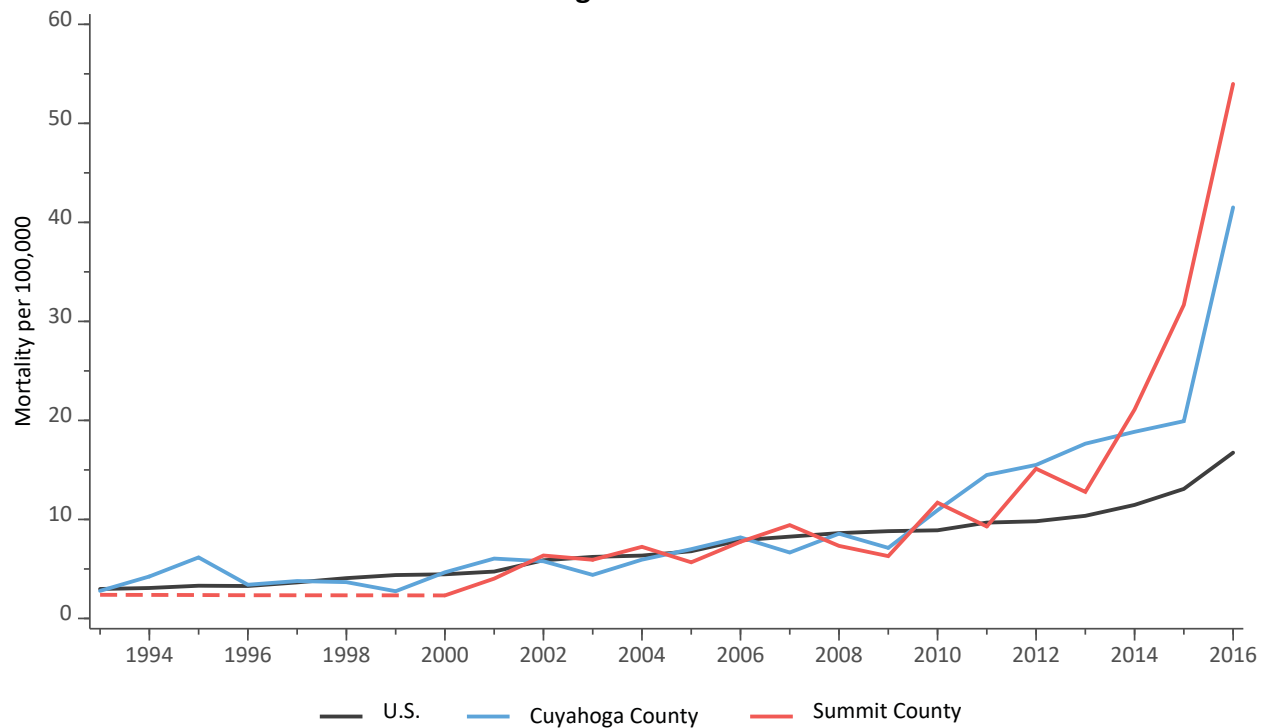
Source: ARCOS and Census Data

65. As seen in **Figure I.11**, while mortality increases in the Bellwether counties were similar to those observed nationally between the late 1990s through 2010, the mortality increases in both Bellwether counties between 2010-17 far outpaced the large increases observed nationally as these areas were especially hard hit by the transition to illicit opioids. Between 2010 and 2016, the large county opioid mortality rate increased by 88 percent while the opioid mortality rate in Cuyahoga County increased by 280 percent and that in Summit County

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increased by 362 percent.⁸⁷ Both Bellwether communities were among the 7 percent of counties with the highest opioid mortality rates in the U.S. in 2016.⁸⁸

Figure I.11
Opioid Mortality Rates: Bellwether Counties v. U.S.
Large Counties



Note: Due to confidentiality restrictions, for any years in which the number of deaths is fewer than 10, rates are adjusted to assume 10 deaths. These years are indicated with a dashed line.
Source: NCHS Mortality Data

66. Cuyahoga and Summit counties are representative of a broader set of communities in Ohio and neighboring areas that were hard hit by the emergence of heroin and fentanyl after 2010. According to reports from the Ohio Substance Abuse Monitoring Program (OSAM), powdered heroin has been the predominant product form of heroin in the Bellwether

⁸⁷ Calculated from NCHS MCODE data.

⁸⁸ Calculated from NCHS MCODE data.

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communities throughout this period and was widely available in the areas prior to 2010.⁸⁹ This indicates that the area was already served by an extensive network of drug traffickers prior to 2010 and that opioid users in the area were amenable first to the substitution of powdered heroin for prescription drugs and then subject to drug traffickers' substitution of fentanyl for heroin. The increase in demand, in turn, induces existing dealers to expand their existing operations and expand into new areas, and induces new entry into the marketplace.⁹⁰

67. For example, the OSAM report for the Akron Region for January through June 2011, around the start of the general decline in prescription opioid sales, stated that:

"Participants reported that overall availability of heroin has increased over the past six months. Participants stated, 'Heroin [availability] has skyrocketed; Instead of my calling a few people to find it [heroin], they call me, they [dealers] come to me.' Participants commonly cited that due to efforts to make intravenous use of prescription opioids more difficult (changing the formulation of OxyContin®), heroin use and availability have increased: 'Because they [Purdue Pharma] changed Oxy's [OxyContin®], pills [prescription opioids] are harder to get. People [users] are changing to heroin.'"⁹¹

68. As shown in **Figure I.12**, which plots NFLIS data on fentanyl identified in drug seizures by law enforcement in 2017, Ohio has the highest rate of fentanyl seizures per capita in the U.S.

⁸⁹ For example, the Ohio Substance Abuse Monitoring (OSAM) Report for the OSAM Report for the Cleveland Region for January-June 2006 states "there has been a dramatic increase in the availability of heroin throughout Cuyahoga County in the past several years." (OSAM, "Surveillance of Drug Abuse Trends in the State of Ohio," January 2006 – June 2006, p. 41) OSAM's June 2008-January 2009 report for Cleveland reported "[t]he Cleveland area crime lab reported overall high and stable heroin availability." (OSAM, "Surveillance of Drug Abuse Trends in the State of Ohio," June 2008 – January 2009, p. 34) The OSAM report for the Akron Region for January through June 2006 noted: "According to law enforcement officers, the current availability of heroin in Summit County remains high in the cities and college areas, with the supply coming in from Chicago, Detroit, Cleveland, and New York City." (OSAM, "Surveillance of Drug Abuse Trends in the State of Ohio," January 2006 – June 2006, p. 5)

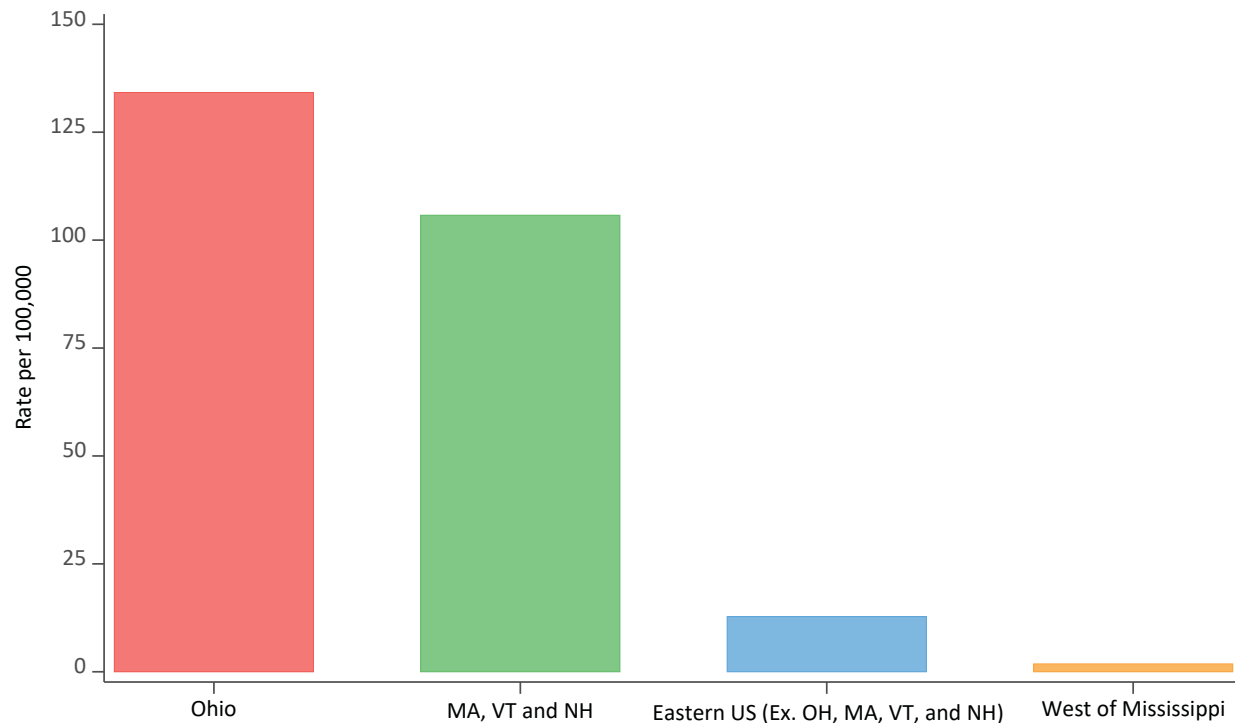
⁹⁰ This is an example of increases in demand for illicit opioids generating "thickness" in markets for heroin. For a discussion of this and related concepts see, for example, Neeman, Zvika, Nir Vulkan, and Alvin E. Roth, *The Handbook of Market Design*, Oxford University Press (2013), p. 3.

⁹¹ OSAM, "Drug Abuse Trends in the Akron-Canton Region, January-June 2011," p. 14.

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As of 2017, fentanyl also emerged on a widescale basis in Massachusetts/New Hampshire/Vermont, with seizures per capita substantially lower in other regions.

Figure I.12
2017 Fentanyl Confiscations Per Capita
NFLIS Data



Notes: (1) Rates reflect fentanyl substances included in top 60 NFLIS substances identified. (2) Fentanyl substances include 4-Fluoroisobutryl fentanyl, Acetyl fentanyl, Acryl fentanyl, Carfentanil, Cyclopropyl fentanyl, Fentanyl, and Furanyl fentanyl.

Source: U.S. Drug Enforcement Administration, Diversion Control Division.

69. The emergence of fentanyl in Ohio in turn led to adulteration of heroin supplied in the region as well as widespread growth of counterfeit prescription opioids.⁹² For example, an

⁹² A few of many examples include counterfeit pills identified in Cleveland (Eric Heisig, "Elyria drug ring sold fentanyl made to look like Percocet pills, feds say," *Cleveland.com*, June 27, 2018, available at https://www.cleveland.com/court-justice/index.ssf/2018/06/elyria_drug_ring_sold_fentanyl.html); Summit County (Darcie Loreno, "Authorities: 3 arrests helped save 1,500 lives after fentanyl pills were stamped to look like Oxycodone," *Fox 8 Cleveland*, May 3, 2018, available at <https://fox8.com/2018/05/03/authorities-3-arrests-saved-1500-lives-after-fentanyl-pills-were-stamped-to-look-like-oxycodone/>); and Cuyahoga County (Kaylyn Hlavaty, "The Cuyahoga County Medical Examiner's Office detects Carfentanil in fake OxyContin pills," *News 5 Cleveland*, July 26,

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OSAM report from June 26 noted that “[p]articipants and community professionals throughout OSAM regions continued to note fentanyl as a top cutting agent for heroin. Respondents explained that fentanyl is cut into heroin to increase both the potency and the amount of the drug to increase profits for the dealer.”⁹³

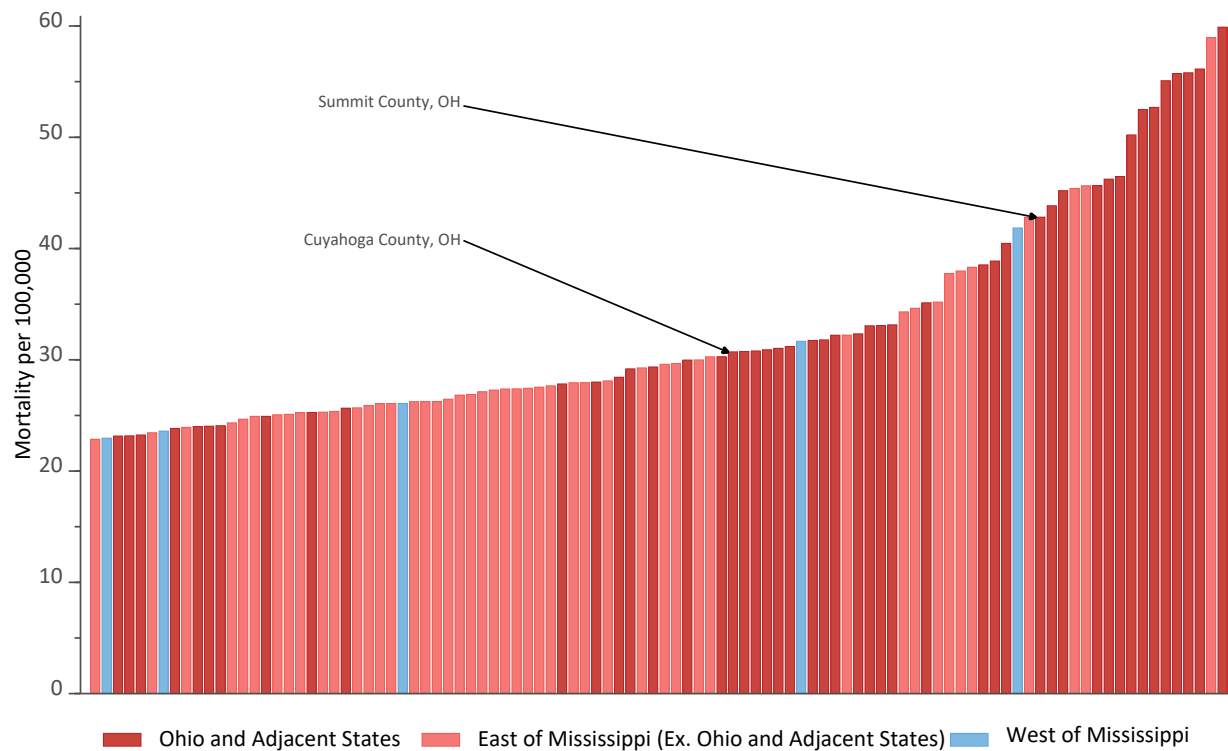
70. Due to the high potency and irregular quality of fentanyl, the adulteration of the heroin supply and the use of fentanyl in counterfeit prescription opioids contributed to the rapid growth in opioid mortality in Cuyahoga and Summit counties and surrounding areas. For example, among the 100 counties in the U.S. with more than 100,000 residents with the highest opioid mortality in 2015/16, fully 48 were in Ohio or adjacent states. See **Figure I.13**.

2017, available at <https://www.news5cleveland.com/news/local-news/oh-cuyahoga/carfentanil-disguised-as-fake-oxycontin-could-lead-to-unintended-overdoses-medical-examiner-says>).

⁹³ OSAM, “Surveillance of Drug Abuse Trends in the State of Ohio January – June 2016”, available at https://mha.ohio.gov/Portals/0/assets/Research/OSAM-TRI/2016-June-Executive-Summary_01312017.pdf.

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Figure I.13
Opioid Mortality Rates in 100 Large Counties with Highest Rates in 2015/16



Note: Adjacent States are PA, WV, KY, IN, and MI.
Source: NCHS Mortality Data

71. As discussed further below, Ohio and adjacent states were at the receiving end of transshipments of prescription opioids from Florida via the “Oxy Express.” Shipments to Florida started to decline sharply in early 2010 with the increase in enforcement against pill mills and fell nearly 52 percent between the peak in Q2 2010 and Q2 2013. In contrast, calculations based on ARCOS data indicate that shipments declined only 4 percent outside of Florida over the same period.⁹⁴ The reduction in transshipments to the area from Florida, together with

⁹⁴ See also MNK-T1_0000467377-78. This internal Mallinckrodt document shows a sharp decrease in oxycodone sales to Florida in the beginning part of 2011, with most other states remaining relatively the same.

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the historical prevalence of powder heroin, contributed to the increase in demand for heroin and the resulting increase in the supply of fentanyl in Ohio and surrounding areas.

IV. The Impact of Shipments on Opioid Dependence

72. In this section and the next I show that the increases in shipments of prescription opioids was a direct and substantial cause of the rapid growth in mortality from both licit and illicit opioid-related mortality in the past 20 years. The relationship between the rapid rise in prescription opioid shipments and the increase in opioid-related mortality since the mid-1990s is readily apparent when comparing differences across geographic areas in opioid shipments received between 1997-2010 and the growth of opioid dependence and mortality. The discussion here identifies and illustrates these major trends. The Cutler Report presents a more detailed statistical analysis of these trends. As discussed further below, in addition to experiencing higher opioid-related mortality, geographic areas that received more shipments over this period also experienced higher crime.

A. Per Capita Shipments of Prescription Opioids Vary Widely Across Geographic Areas

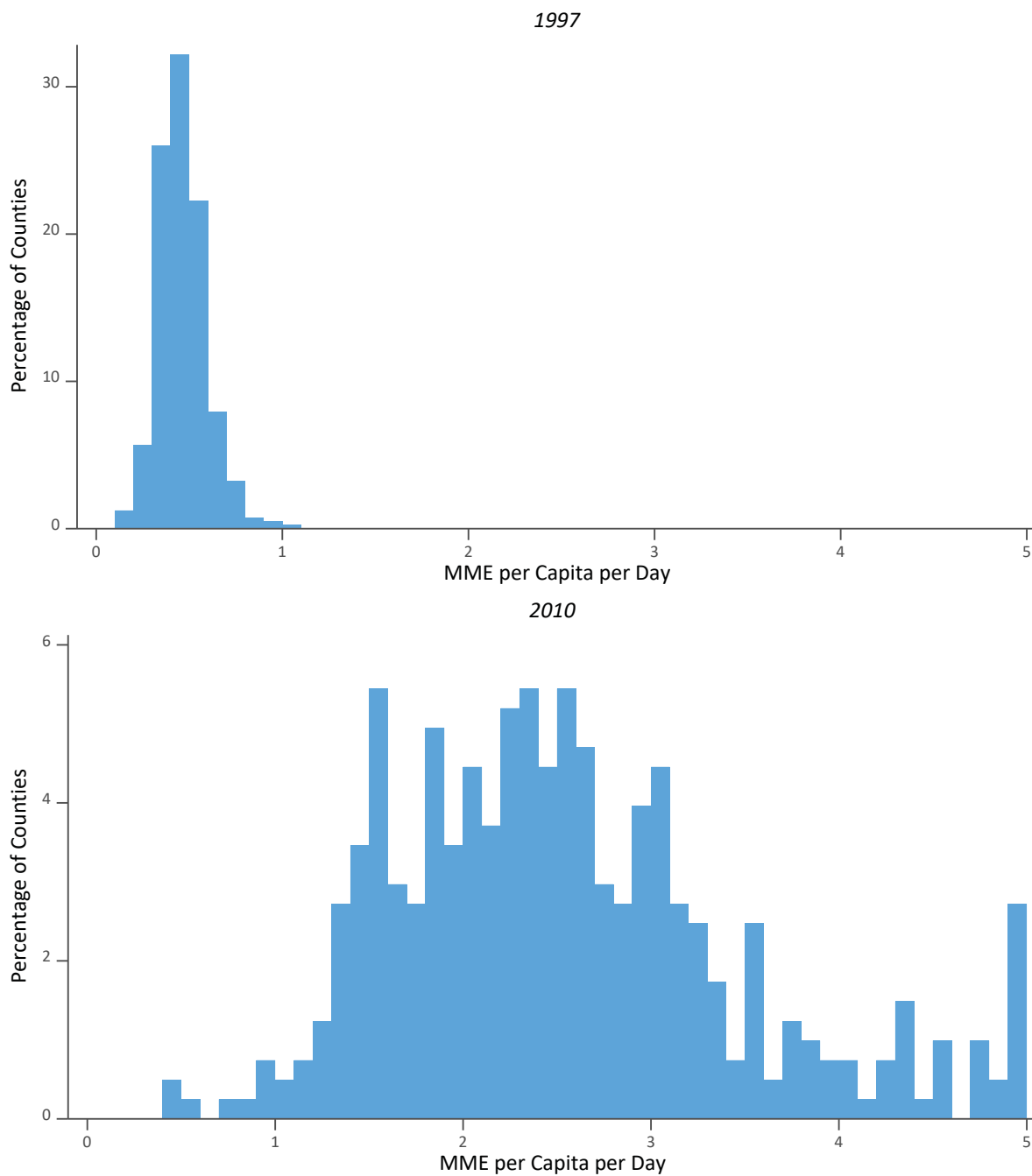
73. For background, while per capita shipments of prescription opioids measured on a national basis grew rapidly nationwide between the mid-1990s and 2010, there was extreme variation in the growth in shipments across counties. **Figure I.14** compares the distribution of prescription opioid shipments, measured in MMEs per capita per day, across large counties in 1997, the first year of available data, and 2010, the peak shipments year. This figure demonstrates that in 2010 nearly all counties had per capita shipments that exceeded that of the counties with the highest level of shipments in 1997. It further demonstrates that the

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growth in shipments was generally increasing in all areas. As this indicates, the growth in per capita shipments varied widely across counties with some counties experiencing much larger increases than others. For example, while per capita shipments increased by 442 percent between 1997 and 2010 across all large counties, shipments grew by 701 percent among the 25 percent of large counties with the highest growth per capita growth. And among the 25 percent of large counties with the slowest growth, per capita shipments still increased by 281 percent.

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Figure I.14
Distribution of Opioid Shipments per Capita
Large Counties



Source: ARCOS

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74. The extreme variation in per capita shipments across areas suggests that prescription activity, which drives shipments to an area, bears little relationship to medical need. Some variation in per capita shipments across counties is expected due to differences in pain management needs, which are correlated to the demographic characteristics of the population. For example, a county with an older population would be expected to have greater demand for prescription pain medications. However, differences in the demographic and economic characteristics of counties explain very little of the observed differences in per capita shipments.

75. To evaluate the extent to which variation in per capita shipments can be explained by such factors, I use regression analysis to evaluate the relationship between the demographic and economic characteristics of counties and county-level shipments per capita in 2010. The analysis is based on the large county sample. I then construct adjusted measures of per capita shipments that control for these differences by evaluating the expected level of shipments in each county assuming that all counties had the average levels of the demographic and economic variables. If these demographic and economic characteristics are important, then the variation across counties in the adjusted rates would be much smaller than the variation in the unadjusted rates.

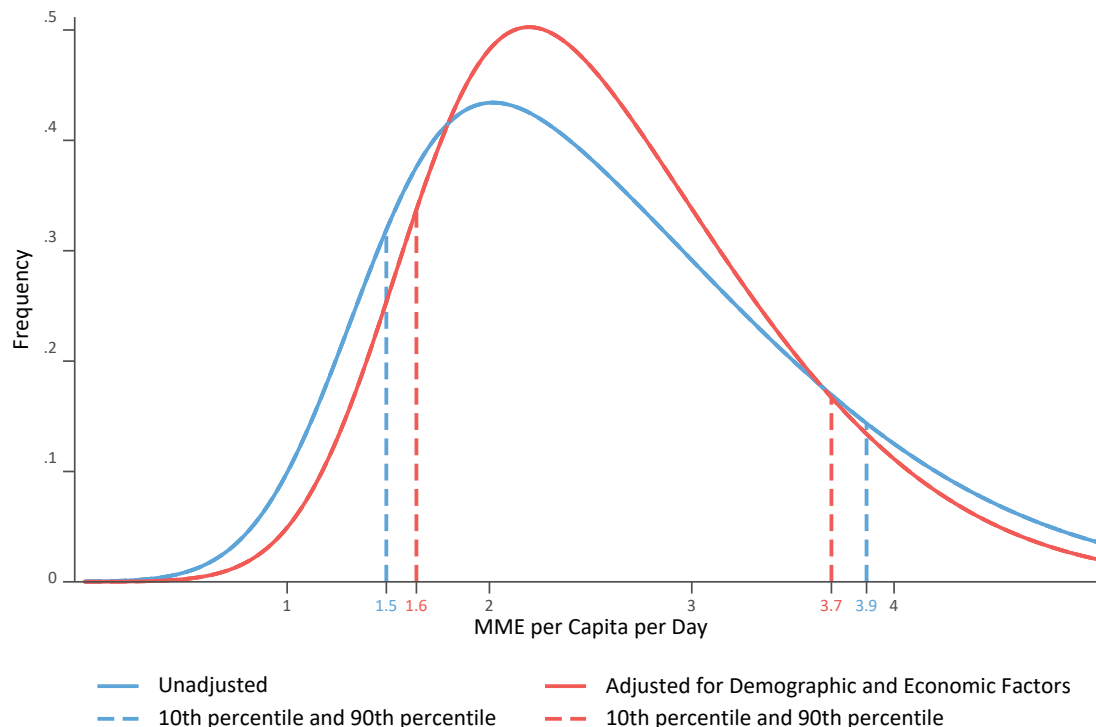
76. In fact, the variation in the adjusted rates is only marginally smaller than that of the unadjusted rates, indicating that economic and demographic differences across counties explain little of the variation in per capita shipments across counties.⁹⁵ As shown in Figure I.15,

⁹⁵ Regression results are reported in **Appendix I.D.**

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per capita MMEs per day at the 10th and 90th percentile of the distribution across all counties in 2010 were 1.5 and 3.9 respectively. That is, counties near the upper end of the distribution of per capita shipments had 2.6 times daily MMEs of counties near the lower end. After accounting for economic characteristics and demographic differences in population characteristics across counties, daily MMEs per capita at the 10th and 90th percentile of the distribution across all counties was 1.6 and 3.7, so counties near the upper end of the distribution of per capita shipments still were 2.3 times that of counties near the lower end of the distribution.

Figure I.15
Distribution in Shipments Per Capita in 2010
With and Without Adjustment for County Demographic Characteristics
Large Counties



Source: ARCOS

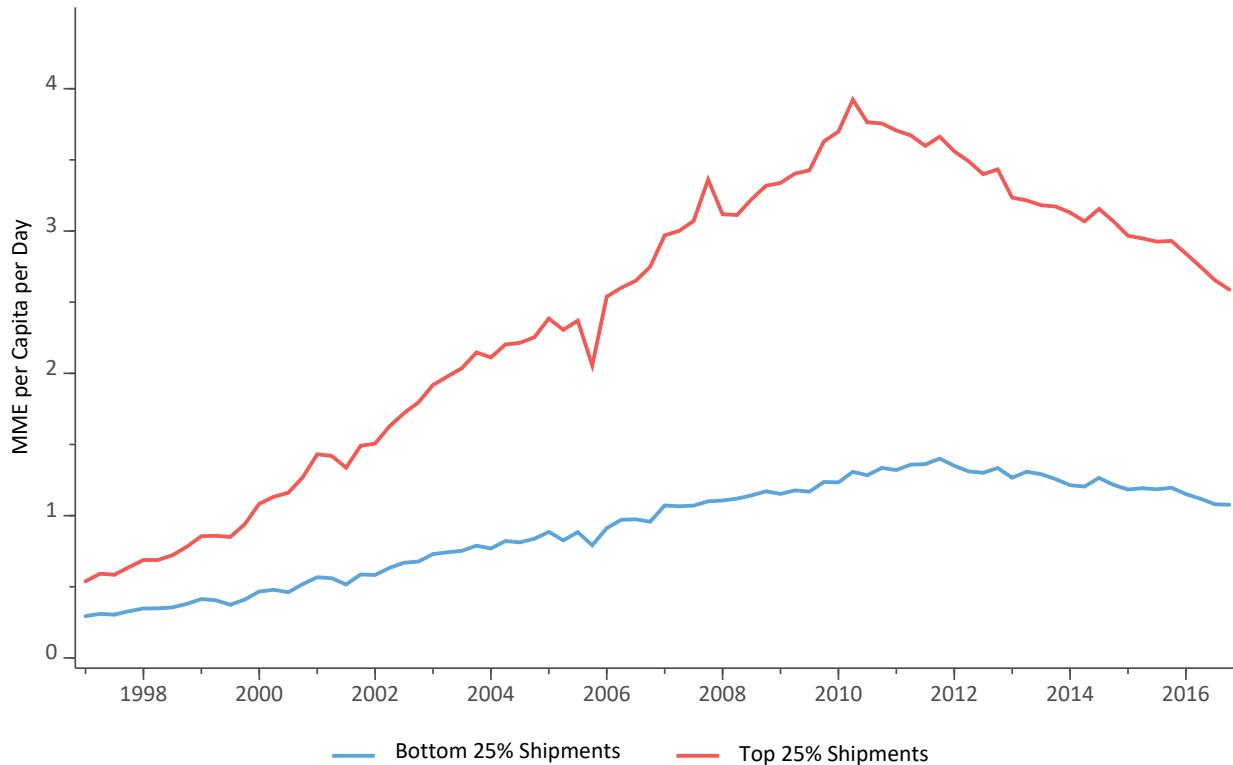
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77. In sum, the wide variation in daily per capita MMEs across counties after controlling for differences in demographic and economic characteristics indicates that many shipments were excessive and unnecessary.

78. As these data imply, there are wide differences across counties in the growth of per capita shipments over time. This is demonstrated further in **Figure I.16** below, which compares “high shipment” to “low shipment” areas. In particular, the figure shows the change over time in per capita shipments of prescription opioids for the quarter of counties (weighted by population) with the highest per capita shipment rates on average from 1997-2010, and the quarter of counties (again weighted by population) with the lowest per capita shipment rates on average over the same time period. As the figure indicates, there was only a modest gap between these groups of counties in per capita shipments in Q1 1997, but the gap widened dramatically, and by Q4 2010 counties in the top quartile had per capita shipments that were more than 2.9 times greater than those in the lower quartile. Furthermore, aggregate shipments of prescription opioids fell between 2011-16 in both categories. As **Figure I.16** shows, shipments in “high shipment” areas started to decline earlier and fell more than those in the “low shipment” areas.

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Figure I.16
Opioid Shipments per Capita by County Shipment Category
Large Counties



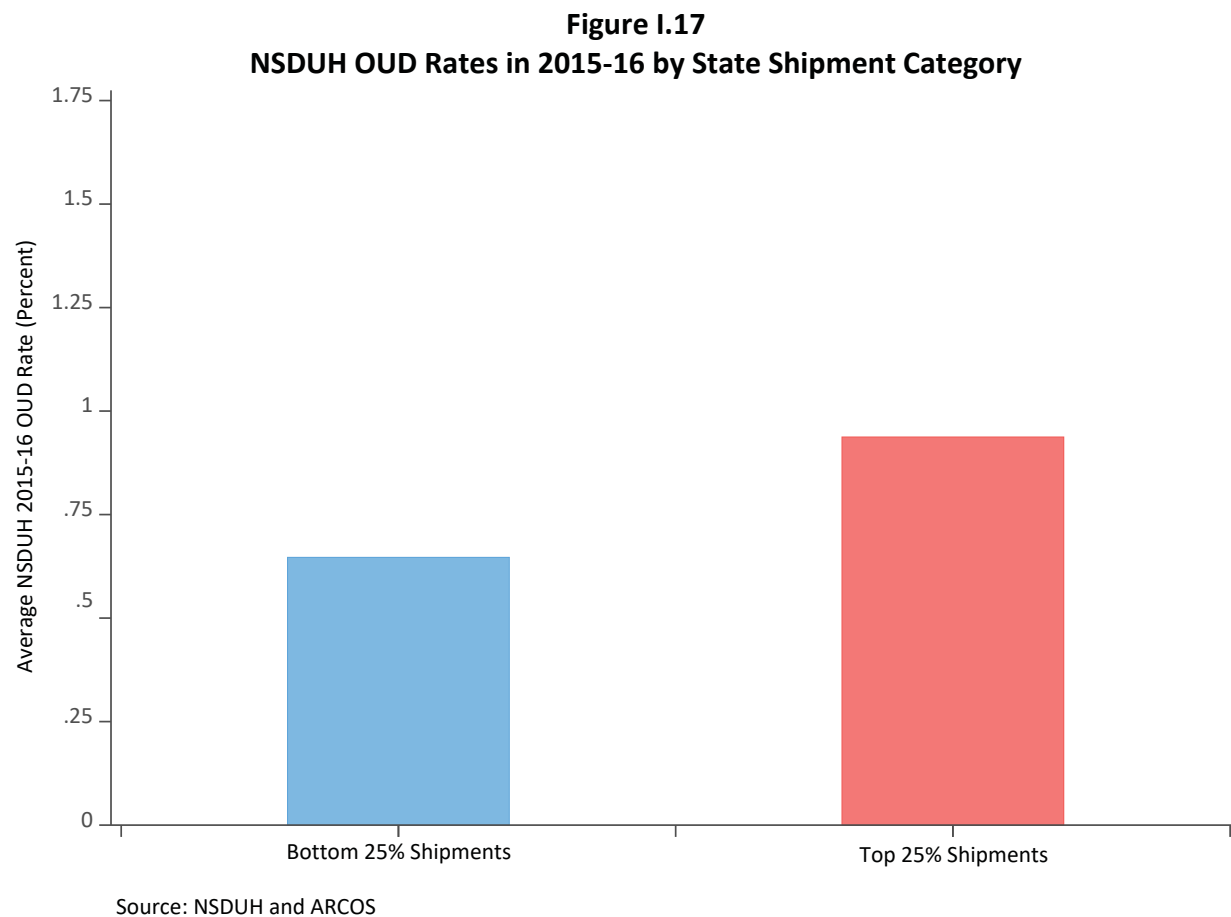
Source: NCHS Mortality Data, ARCOS and Census Data

B. Self-Reported OUD is Higher in Areas with Greater Shipments

79. SAMSHA's NSDUH survey data provide information on self-reported use of opioids and other drugs. As discussed above, others have noted that these data substantially understate the use of opioids and other drugs, and that changes in definitions complicate historical comparison using these data. Nonetheless, data are available that can be used to compare OUD, as measured from NSDUH data, in states with higher and lower levels of prescription opioid shipments.

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80. **Figure I.17** presents a graphical summary, comparing OUD rates in 2015/16 in the 25 percent of states (population weighted) with the highest shipments in 1997-2010 and the 25 percent of states (population weighted) with the lowest shipments in 1997-2010. The analysis indicates that states that received more shipments of prescription opioids in 1997-2010 had higher rates of OUD.



81. Nevertheless, a concern with a simple cross-sectional comparison of this type is that high shipments states may differ from low shipment states in ways that are unobserved but are nonetheless correlated with the rate of OUD, resulting in potentially misleading estimates of the relationship between shipments and opioid misuse.

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These data limitations motivate examining the relationship between shipments and opioid-related outcomes through an additional approach.

C. Opioid-Related Mortality Grew Faster in Areas that Received More Shipments

82. To remedy this potential limitation of cross-sectional analysis, I evaluate changes over time in opioid mortality across different geographic areas. As noted above, such an approach is not possible with NSDUH data, given the data limitations as well as absence of geographic detail at sub-state levels. Hence for this analysis, I turn to another measure of opioid dependence: opioid-related mortality. In particular, I ask whether areas that received more shipments of prescription opioids have higher rates of growth of opioid mortality.

83. While this approach identifies substantial differences in opioid mortality rates in areas that received higher and lower levels of shipments, it comes with an important challenge -- comparing shipments across areas does not account for the critical “transshipment” problem that marks the distribution of prescription opioids in the 2000s. For example, at their peak in the second quarter of 2010, shipments per capita to Florida – the highest in the U.S. – were roughly twice the national average. It has been widely recognized that many shipments to Florida were transshipped to other areas, including Ohio, West Virginia, Kentucky and adjacent areas.⁹⁶ Areas served by this “Oxy Express” realized increases in demand for illicit opioids

⁹⁶ Quinones, Sam. *Dreamland: the true tale of America's opiate epidemic*. New York, NY: Bloomsbury Press., 2016, pp. 241-246. This phenomenon is also discussed in Evans et al. (2019) at p. 11. Reports by the Ohio Substance Abuse Monitoring Program (OSAM) found that prescription opioids were being transported from Florida to Ohio for misuse. For example, a January 2011 noted “Across regions, participants report drug dealers sending people to Florida to obtain prescriptions for opioids to sell in Ohio.” (OSAM, “Drug Abuse Trends in the State of Ohio,” June 2010 - January 2011, p. 3.)

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earlier than other areas of the U.S. and to an extent greater than that implied by measures of shipments to these areas. This will induce some measurement error into my comparisons, reducing the power of shipments to distinguish high versus low use areas. To some extent, I address this measurement error by comparing only the highest and lowest shipment areas in the large county sample discussed above.⁹⁷

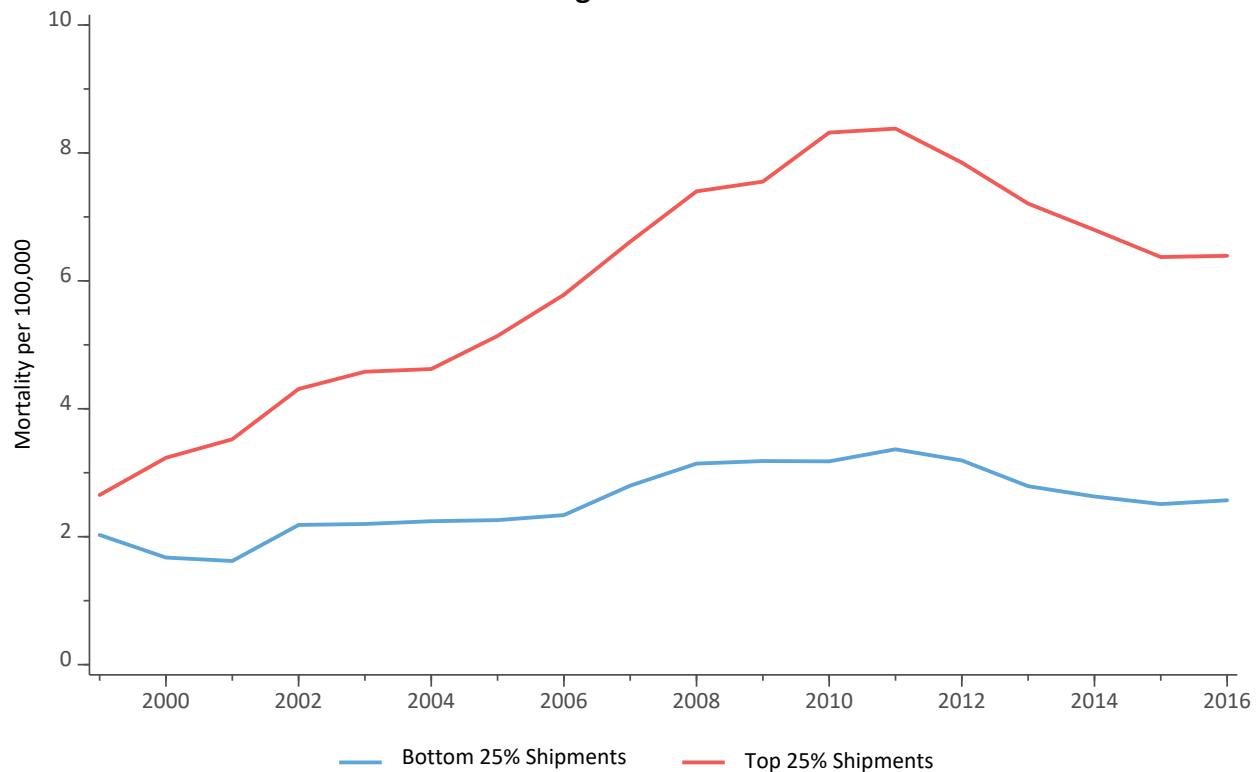
84. Figures **I.18 – I.20** compare alternative measures of opioid mortality rates across counties with the highest per capita shipments between 1997-2010 that account for 25 percent of the population and those with the lowest shipments that account for 25 percent of the population. **Figure I.18** compares prescription opioid mortality rates between these high and low shipment areas from 1999 through 2016. While these areas had similar prescription opioid mortality rates in 1999 and prescription opioid mortality grew everywhere, the increases were much larger in the high shipment areas.⁹⁸ For example, between 1999 and 2010, the prescription opioid mortality rate grew from 2.7 to 8.3 in high shipment areas, an increase of 214 percent, and in low shipment areas, the rate grew from 2.0 to 3.2, which reflects a 57 percent increase, roughly a quarter of the increase observed in high shipment counties.

⁹⁷ This analysis excludes data from four counties that are outliers with respect to the level of per capita shipments. This exclusion follows the approach used in the statistical analysis presented in the Cutler Report. Inclusion of these counties would not materially modify the results or conclusions discussed here. As noted, I use shipments of prescription opioids as a proxy for consumption in an area. The use of proxy variables of this type is common in economic and econometric analysis. Here, the observed relationship between opioid shipments and mortality across areas is likely to understate the relationship between opioid consumption and mortality across areas (because shipments imperfectly approximate consumption in an area). That is, if anything, analysis based on shipments is likely to understate the true impact of defendants' misconduct on opioid-related mortality.

⁹⁸ Prescription-opioid mortality excludes deaths in which both prescription opioids and heroin or other illicit opioids are identified.

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Figure I.18
Prescription Overdose Mortality Rate by County Shipment Category
Large Counties

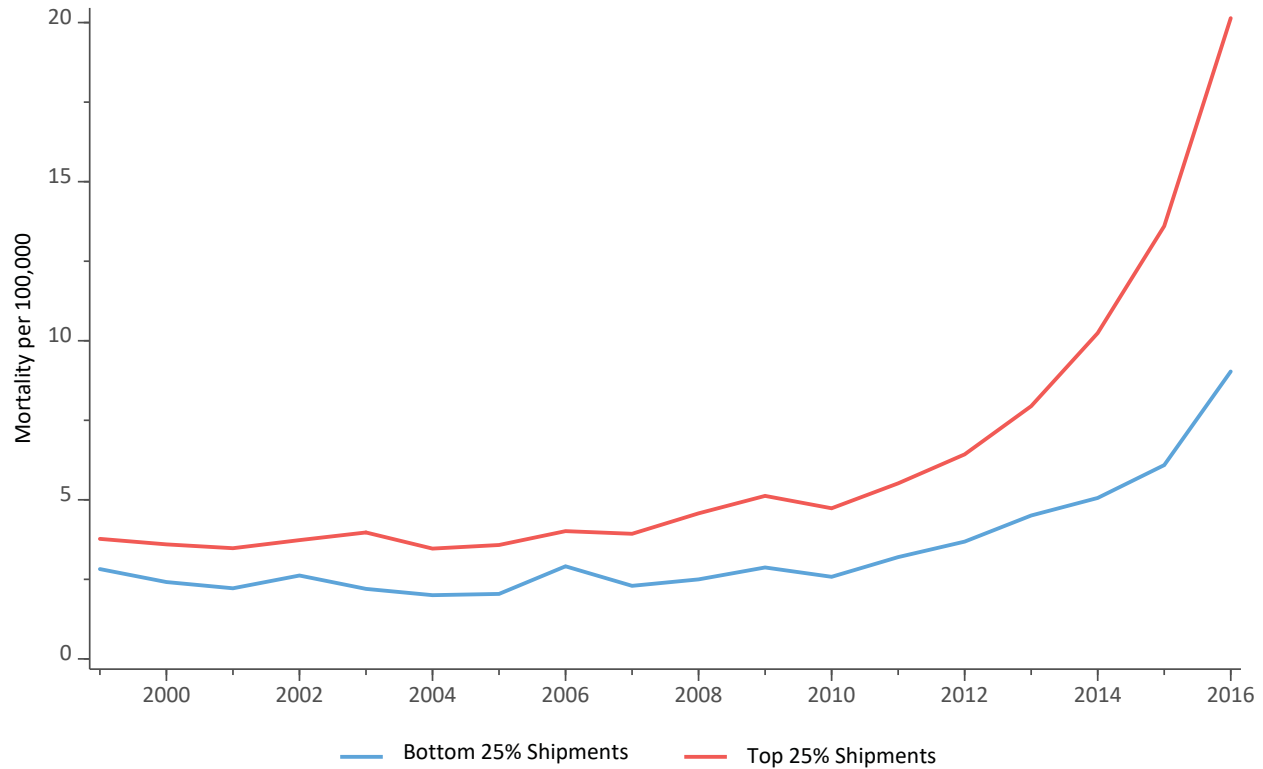


Source: NCHS Mortality Data and ARCOS

85. As discussed above, rising illicit opioid use coincided with declining shipments of prescription opioids and related events around 2010. While the emergence of illicit opioids did not perfectly overlap with areas that received the highest levels of shipments of prescription opioids, changes in illicit mortality generally grew more in areas that received higher shipments. **Figure I.19** shows the trends in mortality from heroin and fentanyl in counties in the top and bottom quartiles with respect to shipments of prescription opioids. The figure indicates that mortality related to heroin and fentanyl moved roughly in parallel in high and low shipment areas prior to 2010, but that mortality from heroin/fentanyl accelerated more in the high shipment counties after 2010.

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Figure I.19
Mortality Involving Heroin or Fentanyl by County Shipment Category
Large Counties

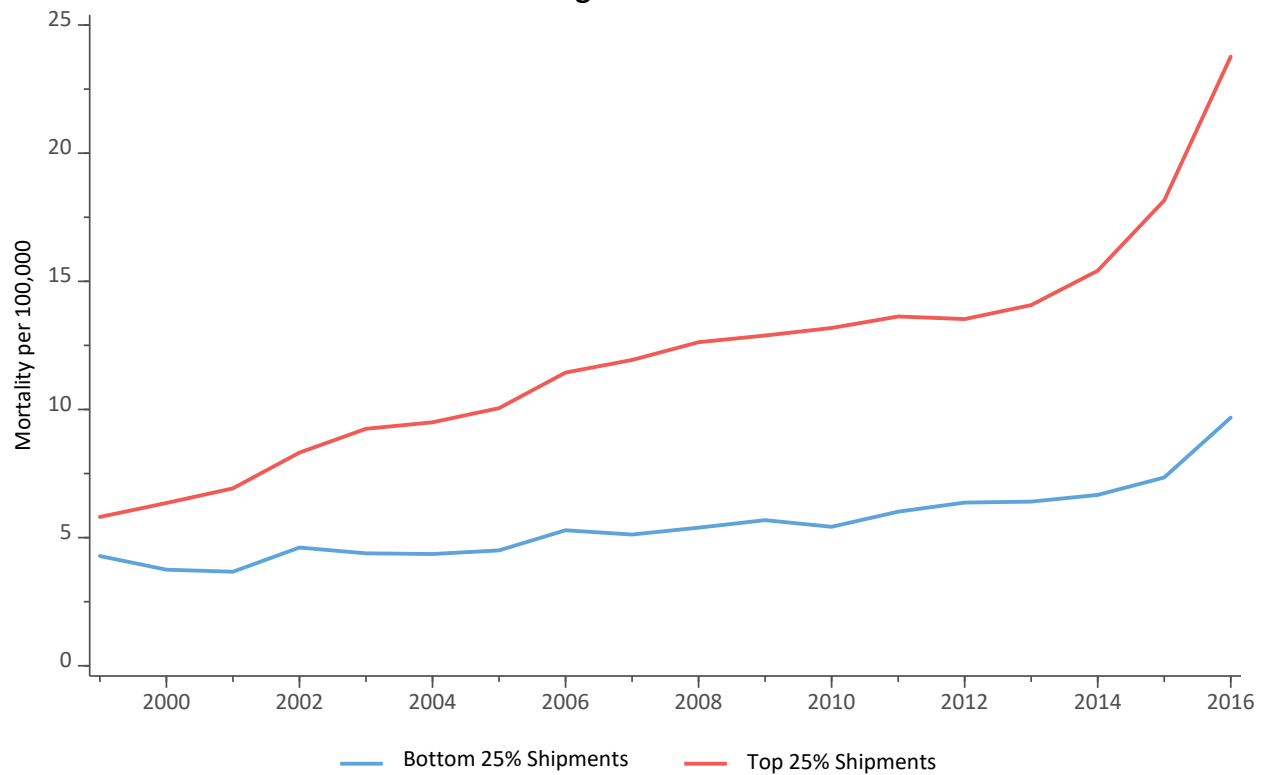


Source: NCHS Mortality Data and ARCOS

86. The growth in total opioid mortality between 1999 and 2016 in the top and bottom quartile shipment quartiles is summarized in **Figure I.20**, which indicates that the gap in opioid mortality between high and low shipment areas was 1.5 per hundred thousand in 1999 and rose to 14.1 per hundred thousand in 2016.

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Figure I.20
Total Opioid Mortality Rate by County Shipment Category
Large Counties



Source: NCHS Mortality Data and ARCOS

87. As these figures indicate, the growth in opioid mortality, including that from prescription and illicit opioids, has a strong relationship with per capita shipments of prescription opioids between 1997-2010, with counties that received more shipments experiencing higher mortality rates.⁹⁹ The Cutler Report provides a statistical analysis of the relationship between shipments and opioid mortality across geographic areas.

⁹⁹ Research by Powell et al. (2017) uses an alternative approach to establish that increased shipments resulted in higher opioid mortality by analyzing the impact of improved access to opioids under Medicare Prescription Drug Benefit Program ("Part D") on non-medical abuse of opioids. Recognizing that states differ with respect to the share of the population eligible for Part D, the study established that states with greater eligibility experienced greater increases in opioid supply and greater opportunities for diversion of shipments by recipients or pharmacies in these states. The study further establishes that such states experience significantly greater growth in opioid overdose deaths and other measures of opioid abuse. The authors conclude: "[w]e find a strong positive

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V. Additional Evidence That the Illicit Opioid Crisis Was the Consequence of Shipments of Prescription Opioids

88. The overview of the opioid crisis in Section III above explains how declining shipments of prescription opioids after 2010 transformed the opioid crisis from one centered on prescription opioids to one involving both prescription and, to an even greater degree, illicit opioids – first heroin and later fentanyl. As shown in **Figure I.4** above, there was no material trend in heroin mortality nationally from 1999 through 2010, but mortality involving heroin accelerated sharply following the end of the dramatic 20-year increase in shipments of prescription opioids.

Additionally, the analysis in Section IV establishes the relationship between prescription opioid shipments and mortality related to both prescription opioids and illicit opioids. This section reviews additional evidence establishing that the illicit opioid crisis would not have emerged in the absence of the prior increase in shipments of prescription opioids.

A. Epidemiological Evidence Establishes the Impact of Prescription Opioids on Heroin Use

89. Several epidemiological studies establish the link between prescription opioids and heroin use. These studies establish that prescription opioids have become the predominant gateway to heroin use, a pattern not observed in earlier decades, and thus that the illicit opioid crisis is a direct result of defendants' misconduct. It is appropriate and standard for a health

relationship between elderly share and the growth in prescription opioids distributed at the state level. [...] Our estimates imply that a 10% increase in medical access to opioids leads to a 7.4% increase in opioid-related mortality and a 14.1% increase in opioid-involved treatment admissions among the under-65 population." (Powell, David, Rosalie Liccardo Pacula, Erin A. Taylor, "How Increasing Medical Access to Opioids Contributes to the Opioid Epidemic: Evidence from Medicare Part D," (April 2017), presented at the National Tax Association's 110th Annual Conference Proceedings, November 2017, available at <https://www.ntanet.org/wp-content/uploads/proceedings/2017/NTA2017-46.pdf>, pp. 1, 5).

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economist to rely on such studies when analyzing public health problems from an economic perspective. I summarize the results of these studies here.

90. Jones et al. (2013), compares NSDUH Survey Data from 2002-04 and 2008-10 and find that heroin use among individuals using opioid pain relievers for nonmedical purposes increased over this period.¹⁰⁰ They find that rates of heroin use among nonmedical users of opioid pain relievers nearly doubled between 2002-04 and 2008-10, from 1.8 percent to 3.4 percent.¹⁰¹ However, no increase in heroin use was seen among people who did not report nonmedical use of prescription opioids in the prior year.¹⁰² The study also establishes that among respondents that reported using both heroin and prescription opioids (for a non-medical use), the share that reported using prescriptions opioids first increased from 64 percent in 2002-04 to 83 percent in 2008-10.¹⁰³

91. In a 2013 study, Muhuri et al. also analyze data from NSDUH and find “a strong association between prior nonmedical use of pain relievers and the subsequent past year initiation of heroin use.”¹⁰⁴ Based on NSDUH survey data from 2002-2011, they find that the heroin incidence rate was 19 times higher among those who reported prior nonmedical prescription pain reliever (NMPR) use than among those who did not report NMPR use.¹⁰⁵ The authors note that “[t]here are many plausible explanations for this finding, including the

¹⁰⁰ Jones, Christopher M. “Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010.” *Drug and Alcohol Dependence* 132 (2013): 95-100. (Jones (2013)).

¹⁰¹ Jones (2013), Table 1.

¹⁰² Jones (2013), Table 1.

¹⁰³ Jones (2013), p. 97.

¹⁰⁴ Muhuri, Pradip K., Joseph C. Gfroerer, and M. Christine Davies. “Associations of nonmedical pain reliever use and initiation of heroin use in the United States.” CBHSQ Data Review 2013 (August). (Muhuri et al (2013))

¹⁰⁵ Muhuri et al (2013), p. 9.

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gateway theory of drug use that posits that the use of some drugs may expose individuals to a repertoire of biological and behavioral factors that could influence their future use of other drugs. In this case, NMPR use may precondition one to engage in heroin use because prescription pain relievers have a similar pharmacological effect as that of heroin, given their similarities in chemical structure.”¹⁰⁶

92. In a 2014 study, Cicero, et al. evaluate survey data of patients in public and private drug treatment centers who reported heroin as their primary drug of abuse.¹⁰⁷ The survey was conducted between 2010 Q3 and 2013 Q3 and covered a population of individuals who had received a primary diagnosis of heroin use/dependence. The survey establishes that among respondents who began using opioids in the 2000s, 75 percent initiated opioid use with prescription opioids, with this share declining to roughly 65 percent for those that initiated opioid abuse in 2010-13.¹⁰⁸ In contrast, among respondents that began using opioids in the 1980s, the comparable figure was roughly 30 percent, and 20 percent for those that began using opioids in the 1960s.¹⁰⁹

93. Additional small-sample epidemiological studies confirm these findings:

- Mateu-Gelabert, et al. (2015) interviewed 46 adults between the ages of 18 and 32 in New York City in 2012-13 who had reported “lifetime use of prescription opioids for

¹⁰⁶ Muhuri et al (2013), p. 14.

¹⁰⁷ Cicero et al (2014).

¹⁰⁸ Cicero et al (2014), p. 823 and Figure 1.

¹⁰⁹ Cicero et al (2014), p. 823 and Figure 1.

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nonmedical reasons.”¹¹⁰ The authors find that 32 out of the 46 individuals (70 percent) eventually began using heroin, which then typically became the primary drug of choice displacing prescription opioids.¹¹¹ The authors claim that for the majority of participants, prescription opioid misuse escalated over time, leading to an increase in intake. As intake increased, coupled with the cost of prescription opioids and availability (and post-2010 pills being more tamper resistant), many participants turned to heroin.¹¹² Nearly all the participants who turned to heroin reported the cost savings as the primary motivation.¹¹³

- Cicero and Ellis (2015) study the impact of abuse deterrent formulations (ADF) of prescription opioids on heroin use among patients in public and private treatment centers.¹¹⁴ The authors note that use of heroin in the past month among respondents steadily increased during the four years after ADF introduction (from approximately 25 percent to 50 percent of respondents).¹¹⁵ Additionally, the authors interview 153 individuals who had indicated prior abuse of OxyContin and among these, 51 indicated the introduction of the ADF led them to shift drug choices. Among those that reported

¹¹⁰ Mateu-Gelabert, Pedro, Honoria Guarino, Lauren Jessell, and Anastasia Teper. “Injection and sexual HIV/HCV risk behaviors associated with nonmedical use of prescription opioids among young adults in New York City.” *Journal of Substance Abuse Treatment* 48 (2015): 13-20 (Mateu-Gelabert et al (2015)), p. 14.

¹¹¹ Mateu-Gelabert et al (2015), p. 14.

¹¹² Mateu-Gelabert et al (2015), pp. 15-16.

¹¹³ Mateu-Gelabert et al (2015), p. 16.

¹¹⁴ Cicero, Theodore J. and Matthew S. Ellis. “Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: Lessons learned from OxyContin.” *JAMA Psychiatry* 72 (2015): 424-430. (Cicero et al (2015)).

¹¹⁵ Cicero et al (2015), Figure 1.

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what drug they switched to, roughly two-thirds switched to heroin because heroin was more readily available and less expensive.¹¹⁶

94. These epidemiological studies discussed above are summarized below in **Table I.1**.¹¹⁷

¹¹⁶ Cicero et al (2015), pp. 426-427.

¹¹⁷ I understand the Expert Report of Dr. Katherine Keyes also references several additional studies showing the high percentage of heroin users that started with prescription opioids, as well as studies showing that nonmedical users of opioids face a higher risk of heroin use.

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Table I.1
Summary of Epidemiological Studies Establishing the Link Between Prescription Opioids and Heroin Use

Study	Data Source	Population Studied	Question Studied	Result
Jones (2013)	NSDUH data (2002-04, 2008-10)	Users and non-users of prescription opioids	Change in rates of past year heroin use from 2002-04 to 2008-10	Rates nearly doubled from 2002-04 to 2008-10 for users of prescription opioids, but remained flat for non-users
		Users of heroin and prescription opioids	Percent of users who initiated opioid use with prescription opioids	2002-04: 64% 2008-10: 83%
Muhuri et al (2013)	NSDUH data (2002-2011)	Populations with and without prior nonmedical prescription opioid use	Heroin incidence rate	Heroin incidence rate is 19 times higher for populations with prior nonmedical prescription opioid use than populations without
Cicero et al (2014)	Data from Survey of Key Informants' Patients (SKIP) program (2010 Q3 - 2013 Q3)	Individuals with primary diagnosis of heroin use/dependence	Percent of heroin users who initiated opioid use with prescription opioids	Respondents who initiated opioid use in 1960s: 20% Respondents who initiated use in 1980s: 30% Respondents who initiated opioid use in 2000s: 75% Respondents who initiated opioid use in 2010-2013: 65%
Mateu-Gelabert et al (2015)	Interview of 46 individuals (New York City 2012-2013)	Users of prescription opioids for nonmedical reasons	Percent of population that transitioned to heroin	Percent that transitioned to heroin: 70%
Cicero et al (2015)	Interviews of 153 participants of the SKIP program	Individuals with primary diagnosis of opioid use disorder and primary drug of abuse is prescription opioid or heroin	Effect of introduction of the abuse deterrent formulation of OxyContin on heroin use	Introduction of abuse deterrent formulation of OxyContin led 51% of interviewees to switch choice of drugs. Roughly 2/3 of this population switched to heroin.

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B. The Economic Literature Recognizes That the Increase in Heroin Mortality after 2010 is Attributable to Shipments of Prescription Opioids

95. As demonstrated above, the rapid growth of mortality from illicit opioids nationally coincided with the reduction in aggregate sales of prescription opioids after 2010. A variety of economic studies have previously established the causal relationship between the increase in heroin-related mortality between 2010 and either 2012 or 2013 and defendants' earlier shipments of prescription opioids, as well as the reduction in sales after 2010.

96. For example, Evans et al. (2019) use monthly data on opioid mortality from the MCODE as well as data on opioids shipments from ARCOS from 2004-2014 to identify changes in the sources of opioid mortality (e.g., the relative increase in illicit mortality) and shipments of prescription opioids. That analysis indicates that acceleration in heroin mortality coincided with the reformulation of OxyContin and the decline in prescription opioid shipments. Evans et al. also evaluate the role of supply side factors on the emergence of heroin by comparing changes in opioid mortality in states classified into four categories based on whether the states are above or below average with respect to historical shipments and above and below average with respect to historical heroin mortality, which is a proxy for the general availability of heroin in the state. They find that, all else equal, states with higher historical levels of heroin mortality experienced larger increases in heroin mortality after 2010. Evans et al. conclude that:

We provide quantitative evidence that the switch to the [abuse deterrent formulation] of OxyContin in August of 2010 led to the increase in the heroin death rate and we find that in states that were at a high risk of substitution from

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opioids to heroin, the reformulation did not reduce the combined heroin and opioid death rate at all.¹¹⁸

97. A related analysis by Alpert, et al. (2018) evaluates the impact of the shipments of prescription opioids on heroin and opioid-related overdose deaths using state level data on opioid-related overdoses and opioid shipments between 1999 and 2013. The analysis uses a panel regression framework to evaluate factors affecting the heroin mortality rate. The authors utilize data from ARCOS on shipments of prescription opioids, MCODE on opioid mortality, and NSDUH on rates of opioid misuse. Alpert et al. conclude that the increase in heroin mortality after 2010 is directly related to earlier shipments of prescription opioids and the 2010 reformulation of OxyContin:

We find that the OxyContin reformulation significantly reduced OxyContin misuse, but also led to a large increase in heroin deaths. States with the highest initial rates of OxyContin misuse experienced the largest increases in heroin deaths. Event study results show that this differential increase in heroin deaths began precisely in the year following reformulation.¹¹⁹

98. The same authors have recently published a follow-up paper in which they have extended their approach to analyze an alternative dependent variable: incidence of infections of hepatitis C. Because hepatitis C is a blood-borne disease frequently contracted through intravenous drug use, the authors speculate that the transition from prescription to illicit opioids explains the large increase in infections observed nationally

¹¹⁸ Evans et al (2019), p. 13.

¹¹⁹ Alpert, Abby, David Powell and Rosalie Lippardo Pacula. "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids." *American Economic Journal: Economic Policy* 2018 10 (2018): 1-35, p. 4.

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since 2010. They find that states with higher levels of OxyContin abuse have experienced much higher growth in infections of hepatitis C since 2010.¹²⁰

99. These studies establish that the illicit opioid crisis that started in 2010 is the direct consequence of the defendants' shipments of prescription opioids in prior years. As noted above, I understand that other expert reports document defendants' knowledge of the link between the illicit opioid crisis post-2010 and prior shipments of prescription opioids.

C. Trends in Opioid Mortality are Largely Unrelated to Economic Conditions, Trends in Non-Opioid Drug Overdoses, and Population Demographics

100. This section evaluates the effect of changes in economic, demographic and social conditions on opioid mortality and establishes that these factors cannot explain the emergence of the illicit opioid crisis in the absence of the prior increase in shipments of prescription opioids. First, I compare trends in opioid mortality in areas with different levels of economic activity in order to evaluate the extent to which opioid mortality trends are related to economic opportunity. Second, I analyze the extent to which increases in opioid mortality are part of a larger trend in drug overdoses.

1. Opioid Mortality and Economic Opportunity

101. The secondary importance of economic conditions as factors driving the crisis, relative to changes in the drug environment, such as the availability of prescription opioids, is stressed

¹²⁰ Powell, David, Abby Alpert, and Rosalie L. Pacula, "A Transitioning Epidemic: How the Opioid Crisis is Driving the Rise of Hepatitis C," *Health Affairs* 38, no. 2 (2019): 287-294.

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by Christopher Ruhm (2018).¹²¹ Ruhm uses county specific data to analyze changes in economic conditions and changes in the drug environment on mortality patterns, including deaths related to opioids, other drugs, suicides and alcohol. The analysis identifies changes in mortality rates of various types using information on shipments of prescription opioids from ARCOS, mortality data from MCODE and census data on the economic and demographic characteristics of areas.

102. Ruhm concludes that economic conditions explain little of the increase in drug mortality in recent decades and that changes in the drug environment, including the availability of prescription opioids, instead account for nearly all of the increases in drug mortality. He finds:

... drug mortality rates did increase more in counties experiencing relative economic decline than in those with more robust growth, but the relationship is weak and mostly explained by confounding factors. In the preferred estimates, changes in economic conditions account for less than one-tenth of the rise in drug and opioid-involved fatality rates. (p. 1)

... the data provide support for the hypothesis that changes in the drug environment have played a key role. During the first decade of the 21st century, rising drug mortality was largely driven by opioid analgesics, but with more recent growth being mostly due to heroin and fentanyl. (p. 41)

103. Ruhm contrasts these findings with the work of Anne Case and Angus Deaton, who have stressed that opioid-related mortality is part of a broader and longer term increase in “deaths of despair,” which include suicides and alcohol-related liver diseases as well as drug overdoses.¹²² Case and Deaton attribute increases in deaths of despair over time “to a broad deterioration in the lives of Americans without a college degree who entered adulthood after

¹²¹ Ruhm, Christopher J. “Deaths of Despair or Drug Problems?” Frank Batten School of Leadership & Public Policy, University of Virginia (January 2018).

¹²² Case, Anne and Angus Deaton, “Mortality and Morbidity in the 21st Century.” *Brookings Papers on Economic Activity* (Spring 2017): 397-476.

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1970.”¹²³ Case and Deaton, however, have responded to Ruhm’s analysis and explain that there is no necessary contradiction between Ruhm’s findings and the “deaths of despair” hypothesis, stating that “[l]ike Ruhm, we directly contradict the idea that deaths are related to economic conditions from 1999-2015 ...”¹²⁴ That is, both Case and Deaton, as well as Ruhm, recognize that the growth in opioid mortality was driven by factors other than changes in macro-economic conditions over this period.

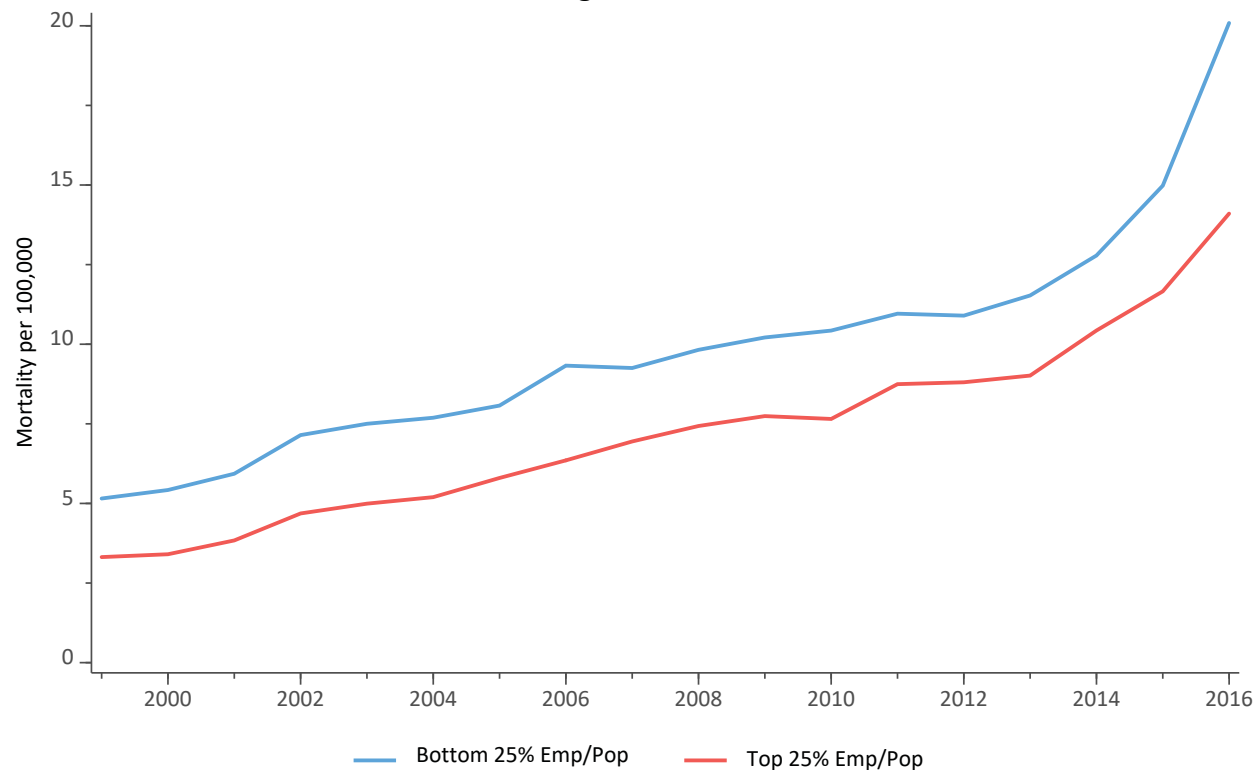
104. **Figure I.21** reports trends in opioid-related mortality between 1999 and 2016 across counties classified based on economic opportunity, as measured by employment rates. The figure plots opioid-related mortality for counties in the top and bottom (population-weighted) quartiles defined with respect to the employment to population ratio. The figure indicates that opioid mortality rates were somewhat higher in areas with lower employment rates throughout the period, but that the growth in mortality was similar in both areas. This pattern is consistent with the conclusions of both Case and Deaton and Ruhm, and it indicates that the increase in opioid-related mortality cannot simply be attributed to differences in economic opportunity between counties.

¹²³ Case, Anne and Angus Deaton, “Deaths of despair redux: a response to Christopher Ruhm,” January 8, 2018 (Case and Deaton (2018)), p. 2.

¹²⁴ Case and Deaton (2018), p. 1.

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Figure I.21
Opioid Mortality Rate by County Employment to Population Ratio Category
Large Counties



Source: NCHS Mortality Data and Census Data

105. The causal relationship between shipments of prescription opioids and the growth of opioid-related mortality (both before and after 2010) demonstrated above, does not imply that factors identified by Case and Deaton as leading to “despair,” including the deterioration in the opportunities of Americans without college degrees, are irrelevant for understanding the opioid epidemic. Case and Deaton argue that the concept of despair is a vague one that is not readily proxied by economic measures. However, the empirical evidence demonstrates that shipments of prescription opioids were a medium through which despair translated to higher deaths. More specifically, while such despair was widespread throughout the nation, deaths grew faster in the high shipment areas.

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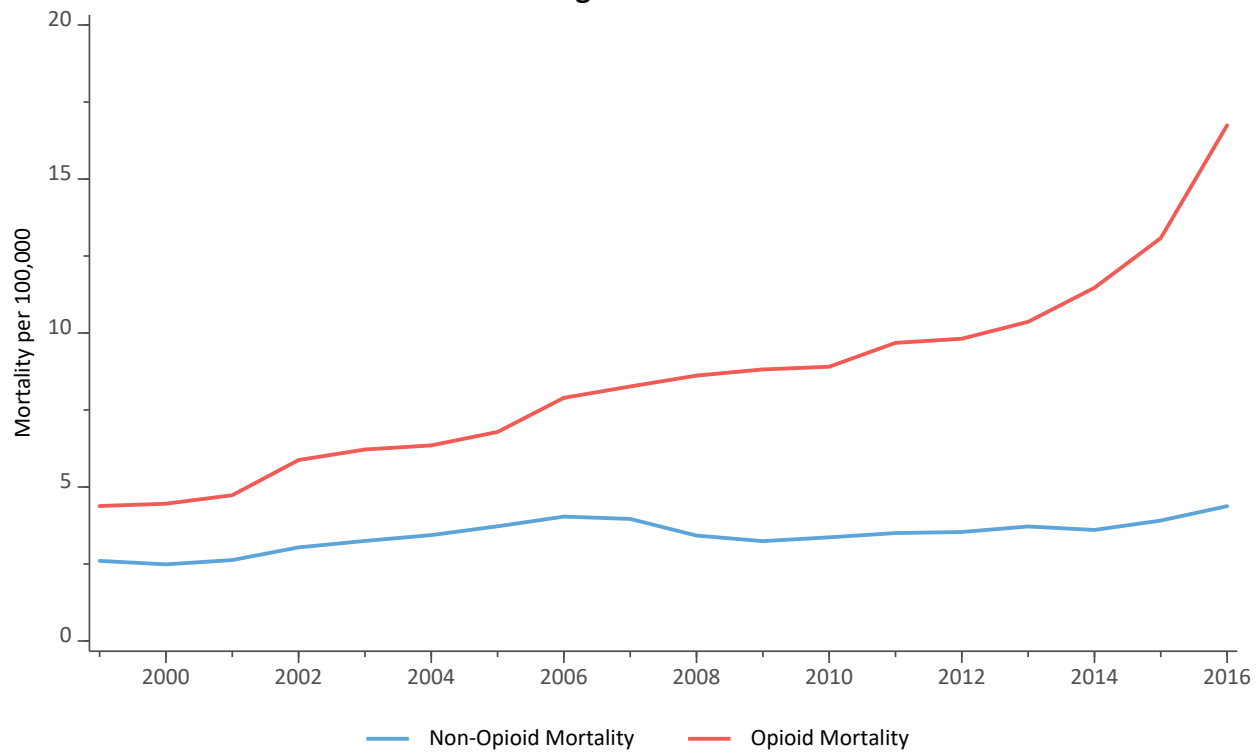
2. Trends in Opioid and Non-Opioid Mortality

106. While economic factors are not sufficient to explain the dramatic increase in opioid-related mortality, that does not preclude the possibility that the increase is related to broader social trends in drug use and drug-related mortality. However, evidence from drug overdose deaths due to non-opioid drugs reflects a very different trend over this time period. **Figure I.22** reports trends in opioid-related and non-opioid¹²⁵ drug overdose mortality for the U.S. between 1999 and 2016. As these data indicate, there were only minor variations in non-opioid drug mortality over time in the U.S. over this period, and no longer term-trend either up or down. In contrast, opioid-related mortality increased dramatically over this period, more than doubling between 1999 and 2010, and then nearly doubling again between 2010-2016.

¹²⁵ Non-opioid mortality is defined as overdoses that do not involve opioids.

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Figure I.22
Opioid and Non-Opioid Overdose Mortality
Large Counties

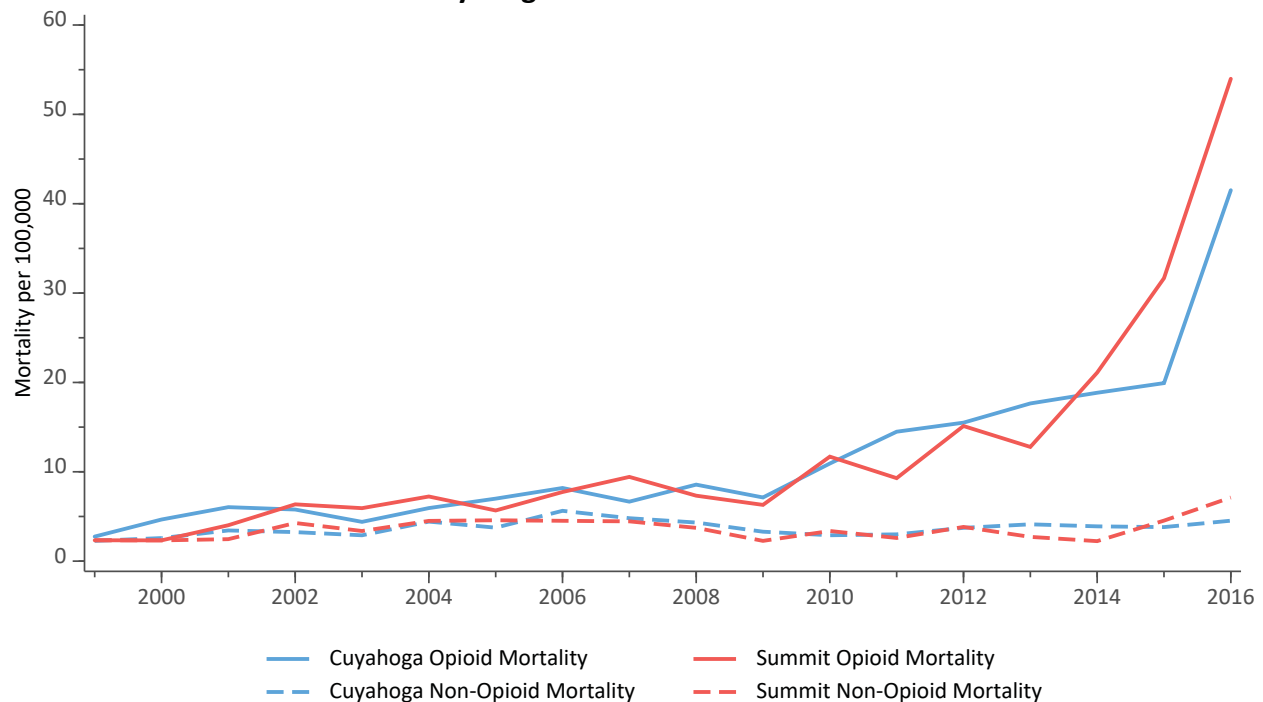


Note: Opioid mortality includes all overdoses that involve opioids.
 Source: NCHS Mortality Data

107. **Figure I.23** compares trends in opioid-related and non-opioid drug overdose mortality for the Bellwether counties. Both areas exhibit no material changes in non-opioid mortality rates over this period despite very large increases in opioid-related mortality. These figures indicate that the increase in opioid-related mortality in both the U.S. and the Bellwether communities cannot be attributed to a more widespread increase in drug mortality over this period. Rather, these results indicate that the shipments of prescription opioids allowed these factors to be translated into opioid-related mortality and related harms.

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Figure I.23
Opioid and Non-Opioid Overdose Mortality
Cuyahoga and Summit Counties



Notes: (1) Opioid mortality includes all overdoses that involve opioids. (2) Due to confidentiality restrictions, for any years in which the number of deaths is fewer than 10, rates are adjusted to assume 10 deaths. This occurs for the Summit Opioid Mortality series in 1999 and 2000 and the Summit Non-Opioid Mortality series in 1999, 2000, 2009, and 2014. Source: NCHS Mortality Data

VI. Shipments of Prescription Opioids Are Associated with Higher Crime

108. The overview thus far focuses on opioid misuse and mortality. However, they are not the only social harms that have occurred as the result of defendants' actions. This section briefly reviews evidence of the link between shipments of prescription opioids and higher levels of crime.

109. The Bellwether governments have responsibilities to enforce criminal laws, and opioids can affect crime through a variety of channels. For example, the purchase, sale or use of prescription opioids for illicit purposes can itself be a crime, as is the purchase, sale or use of illegal opioids such as heroin or fentanyl. Such crimes typically involve willing buyers and sellers

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and thus go unreported, although investigations of such crimes can be a major activity for law enforcement officials. Moreover, opioid misuse is also likely to lead to increases in property crimes (e.g. theft) or violent crimes (e.g. assault or robbery). For example, people using opioids may commit property or violent crimes to finance opioid addiction or because opioid addiction leads people to behavior that they would not otherwise engage in. This section documents the relationship between shipments of prescription opioids and crime using the FBI's UCR database, which is described in the **Data Appendix** attached to this report.

110. Analysis of the impact of the role of shipments of prescription opioids on crime is complicated by the need to disentangle large and widespread declines in both property and violent crimes observed over recent decades. For example, FBI UCR data indicates that violent crime rates fell from 729 to 407 per 100,000 nationally between 1995/96 and 2015/16, a decline of 44 percent, and property crime rates fell from 5,008 to 2,631 per 100,000, a decline of 47 percent.¹²⁶ Moreover, and perhaps not surprisingly, crime rates fell the most in areas that initially had higher levels of crime:

- In counties with the highest violent crime rates that account for 50 percent of U.S. population in 1995/96, the violent crime rates fell by 546 per 100,000 residents between 1995/96-2015/16. Among the counties with the lowest crime rate that account for 50 percent of the U.S. population, the violent crime rates fell by 123 per 100,000 residents.¹²⁷

¹²⁶ Calculated from FBI UCR data.

¹²⁷ Calculated from FBI UCR data.

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- In counties with the highest property crime rates that account for 50 percent of U.S. population in 1995/96, the property crime rates fell by 3,045 per 100,000 residents between 1995/96-2015/16. Among the counties with the lowest crime rates that account for 50 percent of the U.S. population, the property crime rate fell by 1,600 per 100,000 residents.¹²⁸

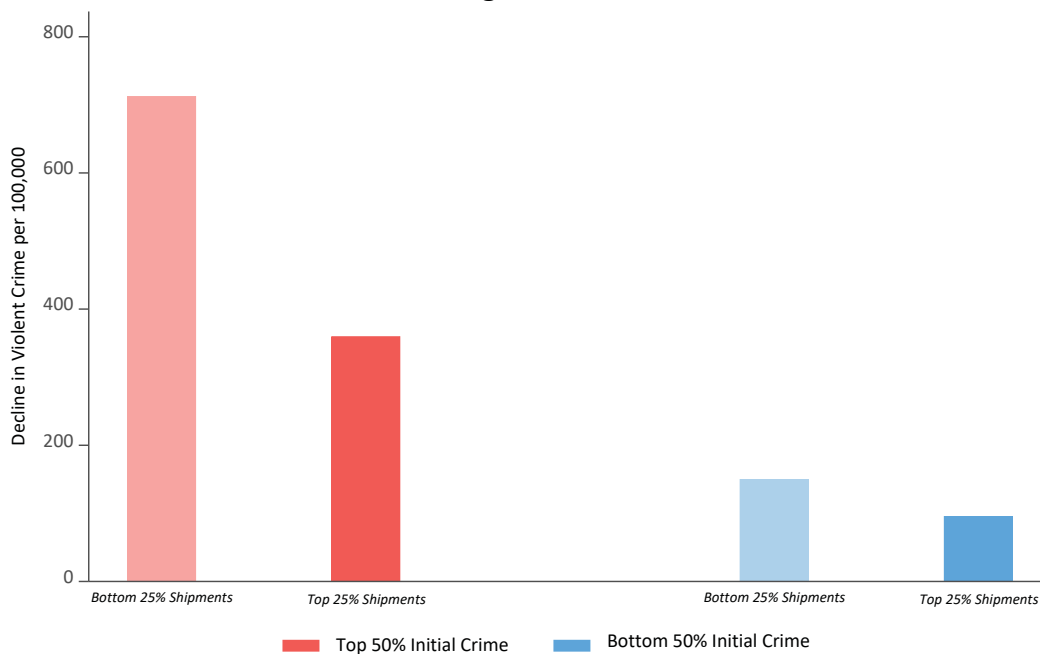
111. Thus, a natural way to evaluate the effects of shipments of prescription opioids on crime is to do so separately for counties with high and low crime rates in 1995. Using this method, I evaluate whether counties that received more shipments between 1997-2010 experienced lower declines in crime than low shipment counties, as would be expected if opioids contributed to increased criminal behavior. Those comparisons are presented in **Figure I.24** and **Figure I.25** for violent and property crime respectively.

- For violent crime, **Figure I.24** shows that in areas with high initial crime, counties that received high shipments experienced declines in crime that were smaller than those that received lower shipments. The same pattern holds for areas with low initial violent crime.
- For property crime, **Figure I.25** shows that in areas with high initial crime, counties that received high shipments experienced declines in crime that were smaller than those that received lower shipments. Similarly, in areas with low initial crime, counties that received high shipments experienced declines in crime that were smaller than those that received lower shipments.

¹²⁸ Calculated from FBI UCR data.

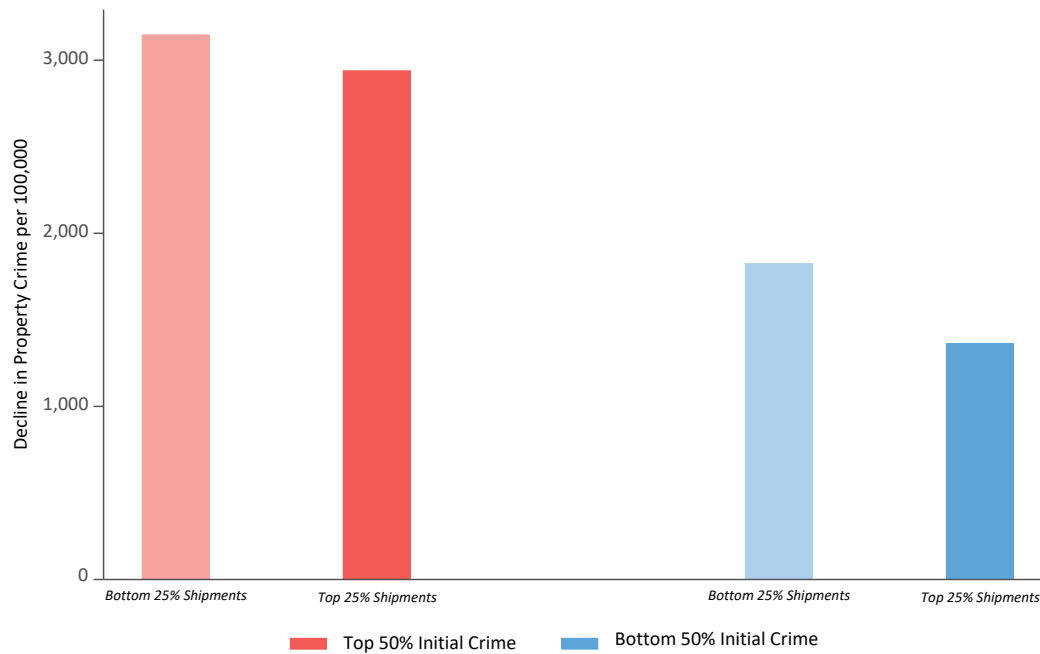
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Figure I.24
Decline in Violent Crime Rates 1995/96 to 2015/16
Large Counties



Source: FBI and Census Data

Figure I.25
Decline in Property Crime Rates 1995/96 to 2015/16
Large Counties



Source: FBI and Census Data

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112. As these figures show, areas with higher shipments generally saw a smaller decline in crime than those areas with lower shipments, after controlling for initial crime rates. The Cutler Report uses a regression analysis to analyze the relationship between changes in crime rates between 1995 and 2016 and establishes that the relationship between shipments and both violent and crime rates is positive and statistically significant.

March 25, 2019



Jonathan Gruber

Appendix I.A: CV and Prior Testimony

JONATHAN GRUBER

MIT Department of Economics
40 Ames Street, E17-434
Cambridge, MA 02142
Phone: 617-253-8892
Fax: 617-253-1330
E-Mail: gruberj@mit.edu
Web: <http://econ-www.mit.edu/faculty/gruberj/>

Personal Information:

Date of Birth: September 30, 1965

Education:

Ph.D. in Economics, Harvard University, 1992
B.S. in Economics, Massachusetts Institute of Technology, 1987

Positions:

Ford Professor of Economics, MIT, 2014-present
Associate Head, MIT Department of Economics, 2018-present
Director, National Bureau of Economic Research's Program on Health Care, 2009-present
Research Associate, National Bureau of Economic Research, 1998-present
International Research Associate, Institute for Fiscal Studies
Board of Directors, iVoted

President, American Society of Health Economists, 2016-2018.
Board of Directors of the Health Care Cost Institute, 2011- 2018
Professor of Economics, MIT, 1997-2014
Margaret MacVicar Faculty Fellow, MIT, 2007-2017
Associate Head, MIT Department of Economics, 2006-2008
Deputy Assistant Secretary for Economic Policy, U.S. Treasury Department, 1997-1998
Castle Krob Associate Professor of Economics, MIT, 1995-1997
Assistant Professor of Economics, MIT, 1992-1995
Director, National Bureau of Economic Research's Program on Children, 1996-2009
Faculty Research Fellow, National Bureau of Economic Research, 1992-1998
Board of the Commonwealth Health Insurance Connector Authority, 2006-2015
Executive Committee, American Economics Association, 2010-2012
CBO Long Term Modeling Advisory Group, 2000-2010
Member, NIH Center for Scientific Review Study Section on Social Sciences, 1998-2002
Co-Editor, Journal of Health Economics, 1998-2001
Associate Editor, Journal of Health Economics, 2001-2018
Co-Editor, Journal of Public Economics, 2002-2010
Associate Editor, American Economic Journal: Economic Policy, 2009-2015

Fellowships and Honors:

Elected as a Fellow of the Econometric Society, 2016
 MIT Undergraduate Economics Association Teaching Award, 2007 and 2015
 2013 American Public Health Association Kenneth Arrow Award for the Outstanding Health Economics Paper of 2012
 Named to 100 Most Powerful People in Health Care in the United States, Modern Healthcare Magazine, 2006 and 2012
 Winner of National Institute for Health Care Management Foundation Health Care Research Award, 2012.
 Named “One of the Top 25 Most Innovative and Practical Thinkers of Our Time” by Slate Magazine, 2011.
 Partners Health Care Connected Health Leadership Award, 2011
 Winner of 2009 Purvis Prize from Canadian Economic Association for Best Public Policy Publication of the year
 Elected to the American Academy of Arts and Sciences, 2008
 MIT Undergraduate Economics Association Teaching Award, 2007 and 2015
 Inaugural Medal for Best Health Economist Age Forty and Under, American Society of Health Economists, 2006
 Elected to the Institute of Medicine, 2004
 2003 Richard Musgrave Prize for best paper in National Tax Journal in 2003
 Member of the National Academy of Social Insurance, 1996
 1995 American Public Health Association Kenneth Arrow Award for the Outstanding Health Economics Paper of 1994
 National Science Foundation Presidential Faculty Fellowship, 1995
 Sloan Foundation Research Fellowship, 1995
 MIT Undergraduate Economics Association Teaching Award, 1994
 FIRST Award, National Institute of Aging, 1994
 Harvard Chiles Fellowship, 1991
 Sloan Foundation Dissertation Fellowship, 1990
 National Science Foundation Scholarship, 1987
 Phi Beta Kappa, 1987

Past Expert Testimony

New York vs. Philip Morris. Deposed on January 4, 2016.

Missouri Division of Insurance vs. Aetna, Inc. and Humana, Inc. Testified on May 16, 2016.

Arbitration between Grand River Enterprises and U.S. Government Under NAFTA: Testified January, 2010.

Grand River Enterprises vs. State Attorneys’ General. Deposed January 8, 2009

Freedom Holdings vs. Andrew Cuomo: Deposition, October 30, 2008; Testimony, November,

2008

Non-Participating Manufacturers Adjustment Proceeding: Deposition, December 6, 2005; Testimony, February 2006; Testimony, January 2007

XCalibur vs. Kline: Deposition, December 2005

XCalibur vs. Kansas: Testimony, July 2005

XCalibur vs. Oklahoma: Testimony, April 2005

Department of Justice vs. Philip Morris. Deposed on April 22, 2002; April 23, 2002; September 11, 2003; and April 21, 2005. Testified at Trial on May 10, 2005

Publications in Journals:

“Non-Cognitive Deficits and Young Adult Outcomes: The Long-Run Impacts of a Universal Child Care Program,” forthcoming, *American Economic Journal: Economic Policy* (also available as NBER Working Paper 21571, September 2015) (with Michael Baker and Kevin Milligan)

“Prescription Drug Use Under Medicare Part D: A Linear Model of Nonlinear Budget Sets,” forthcoming, *Journal of Public Economics* (also available as NBER Working Paper #20976, February 2015) (with Jason Abaluck and Ashley Swanson)

“Evaluating Measures of Hospital Quality: Evidence from Ambulance Referral Patterns,” forthcoming, *Review of Economics and Statistics*. (also available as NBER Working Paper #23166, February 2017) (with Joseph Doyle and John Graves).

“The Efficiency Consequences of Health Care Privatization: Evidence from Medicare Advantage Exits,” *American Economic Journal: Policy*, 10(1), February 2018, p. 153-186 (with Mark Duggan and Boris Vabson).

“Delivering Public Health Insurance through Private Plan Choice In the United States,” *Journal of Economic Perspectives*, 31(4), Fall 2017, p.3-22.

“Uncovering Waste in US healthcare: Evidence from Ambulance Referral Patterns,” *Journal of Health Economics*, 54, July 2017, p.25-39 (with Joseph Doyle and John Graves).

“Federal Funding Insulated State Budgets from Increased Spending Related to Medicaid Expansion,” *Health Affairs*, 36, April 2017, p. 1666

“Early Impact of CareFirst’s Patient-Centered Medical Home with Strong Financial Incentives,” *Health Affairs*, 36(3), March 2017, p. 468-475 (with Christopher Afendulis, Laura

Hatfield, Bruce Landon, Mary Beth Landrum, Robert Mechanic, Darren Zinner and Michael Chernew).

“Premium Subsidies, the Mandate and Medicaid Expansion: Coverage Effects of the Affordable Care Act,” *Journal of Health Economics*, 53, March 2017, p. 72-86 (with Molly Frean and Ben Sommers).

“It’s Good to be First: Order Bias in Reading and Citing NBER Working Papers,” *Review of Economics and Statistics*, 99(1), March 2017, p. 32-39 (with Dan Feenberg, Ina Ganguli, and Patrick Gaule).

“Claims-Shifting: The Problem of Parallel Reimbursement Regimes,” *Journal of Health Economics*, 51, January 2017, p.13-25 (with Olesya Fomenko)

“Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program: Reply,” *American Economic Review*, 106(12), December 2016, p. 3962-87 (with Jason Abaluck)

“Disentangling the ACA’s Coverage Effects: Lessons for Policymakers,” *New England Journal of Medicine*, 375: 1605-1608, October 27, 2016 (with Molly Frean and Benjamin Sommers).

“Evolving Choice Inconsistencies in Choice of Prescription Drug Insurance,” *American Economic Review*, 106(8), August 2016, p. 2145-2184 (with Jason Abaluck).

“Does Church Attendance Cause People to Vote? Using Blue Laws’ Repeal to Estimate the Effect of Religiosity on Voter Turnout,” *British Journal of Political Science*, 46(3), July 2016, 481-500 (with Alan Gerber and Dan Hungerman).

“Controlling Health Care Costs Through Limited Network Insurance Plans: Evidence from Massachusetts State Employees,” *American Journal of Economics: Economic Policy*, 8(2), May 2016, p. 219-250 (with Robin McKnight).

“More Insurers lower Premiums: Evidence from Initial Pricing in the Health Insurance Marketplace,” *American Journal of Health Economics*, 1(1), Winter 2015, 53-81 (with Leemore Dafny and Chris Ody).

“Accounting for ‘Lost Pleasure’ in a Cost-Benefit Analysis of Government Regulation: The Case of the Food and Drug Administration’s Proposed Cigarette Labeling Regulation,” *Annals of Internal Medicine*, 162(1), 2015, 64-65 (with Frank Chaloupka and Ken Warner).

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Appendix I.B Materials Considered

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Appendix I.C: Figure Notes

Fig I.1 Shipments of Prescription Opioids in the U.S.: 1997-2016

1. Based on quarterly ARCOS data covering all counties in the U.S. from 1997Q1 to 2016Q4.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.
4. See Data Appendix for additional details on the ARCOS data.

Fig I.2 Shipments of Prescription Opioids in the U.S. by Major Type: 1997-2016

1. Based on quarterly ARCOS data covering all counties in the U.S. from 1997Q1 to 2016Q4.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.
4. See Data Appendix for additional details on the ARCOS data.

Fig I.3 Opioid Overdose Mortality Rate: 1993-2016

1. Mortality rate includes all overdose deaths involving any opioid use.
2. Mortality rates are Ruhm-adjusted and adjusted for change in ICD classification and age.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. See Data Appendix for additional details on the mortality data.

Fig I.4 Heroin Overdose Mortality Rate: 1999-2016

1. Mortality rate includes any overdose deaths involving heroin and not involving fentanyl.
2. Mortality rates are based on monthly data and multiplied by 12 to convert to an annual rate.
3. Mortality rates are Ruhm-adjusted.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Mortality rates are calculated for the entire U.S.
6. See Data Appendix for additional details on the mortality data.

Fig I.5 Heroin Mortality Rate East and West of the Mississippi River

1. Mortality rate includes any overdose deaths involving heroin and excluding fentanyl.
2. Mortality rates are Ruhm-adjusted.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Counties are defined as west of the Mississippi River if they are in one of the following states:
AK, AZ, AR, CA, CO, HI, ID, IA, KS, LA, MN, MO, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, WY.
6. See Data Appendix for additional details on the mortality data.

Fig I.6 Relative Strength of 1 Milligram of Prescription Opioids

1. The relative strength of fentanyl is from footnote 8 of the CMS Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors chart: "The MME conversion factor for fentanyl patches is

based on the assumption that one milligram of parenteral fentanyl is equivalent to 100 milligrams of oral morphine” (<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-Aug-2017.pdf>).

Fig I.7 Share of Drug Confiscations Identified in NFLIS Involving Fentanyl

1. Fentanyl share reflects fentanyl substances included in top 60 NFLIS substances identified divided by total identified top 60 substances.
2. Fentanyl substances include 4-Fluoroisobutyryl fentanyl, Acetyl fentanyl, Acryl fentanyl, Carfentanil, Cyclopropyl fentanyl, Fentanyl, and Furanyl fentanyl.
3. Fentanyl substances are not in top 60 substances in 2011 and 2012.
4. The national rate is aggregated from state-level data which includes all 50 states and District of Columbia.

Fig I.8 Prescription and Illicit Opioid Mortality Rate: 1999-2016

1. Prescription Mortality (Excluding Fentanyl) includes overdose deaths involving prescription opioids excluding overdose deaths that involve fentanyl or heroin.
2. Heroin Mortality (Excluding Fentanyl) includes all overdose deaths involving heroin but not fentanyl.
3. Mortality Involving fentanyl includes all overdose deaths in which fentanyl is identified as a cause of death.
4. All mortality rates are Ruhm-adjusted.
5. Mortality rates are calculated for large counties, as identified by the NCHS.
6. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
7. See Data Appendix for additional details on the mortality data.

Fig I.9 Fentanyl Mortality Rate East and West of the Mississippi River

1. Mortality rate includes all overdose deaths involving fentanyl.
2. Mortality rates are Ruhm-adjusted.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Counties are defined as west of the Mississippi River if they are in one of the following states: AK, AZ, AR, CA, CO, HI, ID, IA, KS, LA, MN, MO, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, WY.
6. See Data Appendix for additional details on the mortality data.

Fig I.10 Shipments of Prescription Opioids: 1997-2016 / Bellwether Counties and U.S. Total

1. Based on quarterly ARCOS data covering all counties in the U.S. from 1997Q1 to 2016Q4.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.
4. See Data Appendix for additional details on the ARCOS data.

Fig I.11 Opioid Mortality Rates: Bellwether Counties v U.S.

1. Mortality rate includes all overdose deaths involving any opioid use.
2. Mortality rates are Ruhm-adjusted and adjusted for change in ICD classification and age.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. See Data Appendix for additional details on the mortality data.

Fig I.12 2017 Fentanyl Confiscations per Capita

1. Fentanyl share reflects fentanyl substances included in top 60 NFLIS substances identified divided by total identified top 60 substances.
2. Fentanyl substances include 4-Fluoroisobutyryl fentanyl, Acetyl fentanyl, Acryl fentanyl, Carfentanil, Cyclopropyl fentanyl, Fentanyl, and Furanyl fentanyl.

Fig I.13 Opioid Mortality Rates in 100 Large Counties with Highest Rates in 2015/16

1. The following states are adjacent to Ohio: PA, WV, KY, IN, MI.
2. The following states are West of the Mississippi: AK, AZ, AR, CA, CO, HI, ID, IA, KS, LA, MN, MO, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, WY.
3. Mortality rate includes all overdose deaths involving any opioid use.
4. Mortality rates are Ruhm-adjusted and adjusted for change in ICD classification and age.
5. Mortality rates are calculated for large counties, as identified by the NCHS.
6. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
7. See Data Appendix for additional details on the mortality data.

Fig I.14 Distribution of Opioid Shipments per Capita

1. Based on quarterly ARCOS data in 1997 and 2010 for counties with at least 100,000 adult population (age 15+) in 1997.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.
4. Counties with greater than 5 MME per capita per day are placed in the 5 MME per capita per day category.
5. See Data Appendix for additional details on the ARCOS data.

Fig I.15 Distribution in Shipments per Capita in 2010

1. Based on quarterly ARCOS data in 2010 for counties with at least 100,000 adult population (age 15+) in 1997.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.

4. The adjusted series is generated by calculating the residuals of a regression of shipments per capita on demographic and economic variables. See Appendix I.D. for regression results.
5. The plotted curves are skew-normal distributions fit to the unadjusted and adjusted shipment distributions. The 10th and 90th percentiles are percentiles of the underlying distributions, not the fitted skew-normals.
6. See Data Appendix for additional details on the ARCOS data.

Fig I.16 Opioid Shipments per Capita by County Shipment Category

1. Based on quarterly ARCOS data from 1997Q1 to 2016Q4 for large counties as identified by the NCHS.
2. Shipments are in Morphine Milligram Equivalents.
3. Shipments per capita are calculated using adult population (age 15+) from the Census Bureau.
4. Bottom and Top 25% quantiles are based on MME per capita and weighted by county adult population.
5. See Data Appendix for additional details on the ARCOS data.

Fig I.17 NSDUH OUD Rates in 2015-16 by State Shipment Category

1. The OUD rate is the percent of NSDUH survey respondents age 12 and older who report having experienced OUD in the past 12 month. The average is weighted by state adult population (age 15+).
2. Bottom and Top 25% quantiles are based on MME per capita and weighted by state adult population.

Fig I.18 Prescription Overdose Mortality Rate by County Shipment Category

1. Mortality rates include overdose deaths involving prescription opioids only.
2. Mortality rates are Ruhm-adjusted.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Bottom and Top 25% quantiles are based on MME per capita and weighted by county adult population.
6. See Data Appendix for additional details on the ARCOS and mortality data.

Fig I.19 Mortality Involving Heroin or Fentanyl by County Shipment Category

1. Mortality rates include all overdose deaths involving heroin or fentanyl.
2. Mortality rates are Ruhm-adjusted.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Bottom and Top 25% quantiles are based on MME per capita and weighted by county adult population.
6. See Data Appendix for additional details on the ARCOS and mortality data.

Fig I.20 Total Opioid Mortality Rate by County Shipment Category

1. Mortality rates include all overdose deaths involving opioids.
2. Mortality rates are Ruhm-adjusted and adjusted for age and changes in ICD definition.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Bottom and Top 25% quantiles are based on MME per capita and weighted by county adult population.
6. See Data Appendix for additional details on the ARCOS and mortality data.

Fig I.21 Opioid Mortality Rate by County Employment to Population Ratio Category

1. Mortality rates include all overdose deaths involving opioids.
2. Mortality rates are Ruhm-adjusted and adjusted for age and changes in ICD definition.
3. Mortality rates are calculated for large counties, as identified by the NCHS.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. Bottom and Top 25% quantiles are based on the employment to population ratio and weighted by county adult population.
6. See Data Appendix for additional details on the employment-to-population ratio and mortality data.

Fig I.22 Opioid and Non-Opioid Overdose Mortality

1. Opioid mortality rate includes all overdose deaths involving any opioids.
2. Non-Opioid mortality rate includes all overdose deaths that do not involve opioids.
3. Mortality rates are Ruhm-adjusted and adjusted for age and changes in ICD definition.
4. Mortality rates are calculated for large counties, as identified by the NCHS.
5. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
6. See Data Appendix for additional details on the mortality data.

Fig I.23 Opioid and Non-Opioid Overdose Mortality – Cuyahoga and Summit Counties

1. Opioid mortality rate includes all overdose deaths involving opioids.
2. Non-Opioid mortality rate includes all overdose deaths involving only non-opioids.
3. Mortality rates are Ruhm-adjusted and adjusted for age and changes in ICD definition.
4. Mortality rates are calculated using adult population (age 15+) from the Census Bureau.
5. See Data Appendix for additional details on the mortality data.

Fig I.24 Decline in Violent Crime Rates 1995/1996 to 2015/16

1. Large counties are defined as counties with at least 100,000 total population in 1995/96.
2. Bottom and Top 50% initial crime quantiles are based on the 1995/96 violent crime rates and are weighted by county total population. Bottom and Top 25% shipment quantiles are based on

MME per capita, are calculated conditional on initial crime quantile, and are weighted by county adult population.

3. See Data Appendix for additional details on the FBI crime and ARCOS data.

Fig I.25 Decline in Property Crime Rates 1995/1996 to 2015/16

1. Large counties are defined as counties with at least 100,000 total population in 1995/96.
2. Bottom and Top 50% initial crime quantiles are based on the 1995/96 property crime rates and are weighted by county total population. Bottom and Top 25% shipment quantiles are based on MME per capita, are calculated conditional on initial crime quantile, and are weighted by county adult population.
3. See Data Appendix for additional details on the FBI crime and ARCOS data.

Appendix I.D: Regression Estimates of Demographic Variables

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Demeaned 2010 Shipments Regression*Demeaned Demographic and Economic Variables***Ordinary Least Squares Regression***Robust Standard Errors*

Number of obs = 404
Adjusted R-squared = 0.26

Variable	Mean	Coef.	Std. Err	t	P> t
MMEs per Capita per Day	2.58				
Percent Male in 2010	-2.09	-5.31	6.37	-.83	.41
Percent Under 15 in 2010	-2.38	-7.06	3.67	-1.93	.05
Percent 15 to 29 in 2010	-2.36	-5.04	3.68	-1.37	.17
Percent 30 to 44 in 2010	-2.38	-4.57	4.56	-1.00	.32
Percent 45 to 64 in 2010	-2.31	-1.27	5.34	-.24	.81
Percent White in 2010	-1.78	-.02	.94	-.03	.98
Percent Black in 2010	-2.44	-1.42	1.00	-1.42	.16
Percent Hispanic in 2010	-2.45	-1.23	.95	-1.29	.20
Percent Less High School in 2010	-2.47	.07	2.49	.03	.98
Percent High School in 2010	-2.21	1.01	1.63	.62	.54
Percent Some College in 2010	-2.35	2.73	2.12	1.29	.20
Employment Ratio in 2010	-2.00	-2.58	2.00	-1.29	.20
Percent Unemployed in 2010	-2.48	5.36	3.37	1.59	.11
Median Household Income (Thousands) in 2010	50.48	-.03	.01	-2.71	.01
Percent Ag/M/Const/Util in 2010	-2.51	.88	1.72	.51	.61
Percent Manufacturing in 2010	-2.47	-2.60	1.11	-2.34	.02
Percent Retail/Transportation in 2010	-2.35	1.84	1.29	1.42	.16
Percent Professional in 2010	-2.34	3.39	1.38	2.46	.01
Poverty Rate in 2010	-2.43	-2.85	3.02	-.94	.35
Percent Urban in 2010	-1.72	1.28	.54	2.37	.02
Census Population (Thousands) in 2010	526.75	.00	.00	-1.34	.18
Constant		-38.28	31.89	-1.20	.23

Source: U.S. Census data; ARCOS

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